

**A prospective open labeled randomized clinical trial on
KALLADAIPPU” (Urolithiasis) with evaluation of trial drug
“SIRU NERUNJIL KUDINEER”**

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**DEPARTMENT OF POTHUMARUTHUVAM
GOVERNMENT SIDDHA MEDICAL COLLEGE
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CERTIFICATE

Certified that I have gone through the dissertation entitled **“A Prospective Open Labeled Randomized Clinical Trial on “SIRU NERUNJIL KUDINEER” for “KALLADAIPPU” (UROLITHIASIS)** submitted by **Dr.T.SEETHA LAKSHMI (Reg. No.321511007)** a student of final year MD(S) Department of Pothu Maruthuvam (Branch-I) of this college and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduce the dissertation submitted and approved earlier.

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DECLARATION

I declare that the dissertation entitled **“A Prospective Open Labeled Randomized Clinical Trial on “SIRU NERUNJIL KUDINEER” for “KALLADAIPPU” (UROLITHIASIS)** submitted for the degree of MD Siddha Medicine of Government Siddha Medical College, Palayamkottai, Tirunelveli, Tamil Nadu (The Tamil Nadu Dr. M.G.R. Medical University, Chennai) the record of work carried out by me under the guidance of **Dr.G.Subash chandran M.D(S), Ph.D.**, Assistant Professor, Department of Pothu Maruthuvam, Govt. Siddha Medical College, Palayamkottai. and under the supervision of **Prof.Dr.A.Manoharan,MD (S), Ph.D.**, Head of the department, Department of Pothu Maruthuvam, Govt. Siddha Medical College, Palayamkottai. This work has not formed the basis of award of any degree, diploma, associates fellowship or other titles in this university or any other university or institution of higher learning.

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Date :

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CONTENTS

Chapter No	Title	Page No
	ABBREVIATIONS	
	ABSTRACT	
I	INTRODUCTION	
1.1	Background	1
1.2	Aim and Objectives	4
II	REVIEW OF LITERATURE	
2.1	Siddha aspect	
	2.1.1. வேறுபெயர்கள் (SYNONYM)	5
	2.1.2 இயல் (DEFINITION)	5
	2.1.3 நோய் வரும் வழி (AETIOLOGY)	7
	2.1.4 பொதுகுறி குணங்கள் (COMMON SYMPTOMS)	9
	2.1.5 வகைகள் (CLASSIFICATION)	9
	2.1.6 Some diseases associated with Kalladaippu Noi in Siddha text	17
	2.1.7 முக்குற்ற வேறுபாடுகள் (PATHOLOGY)	17
	2.1.8 Principles of Siddha Diagnosis in Urolithiasis	19
	2.1.9 நோய் கணிப்பு முறை (DIAGNOSIS AND PROGNOSIS)	20
	2.1.10 எண்வகைத் தேர்வுகள்	21
	2.1.11 நெய்குறி	28
	2.1.12 Line of Treatment Advocated as per the Siddhe Principles	30
	2.1.13 Diet	31
2.2	Modern aspect	
	2.2.1 Urinary System	32
	2.2.2 Urolithiasis	33
	2.2.3 Epidemiology	33
	2.2.4 Aetiology	35
	2.2.5 Types of Urinary Stones	36
	2.2.6 Pathogenesis of Stones	39
	2.2.7 Clinical Symptoms	41
	2.2.8 Diagnosis	42

	2.2.9 Differential Diagnosis	43
	2.2.10 Complications	43
	2.2.11 Medication	43
	2.2.12 Diet for Urinary Stones	44
III	MATERIALS AND METHODS	
3.1	Study designs and conduct of the study	45
3.2	Sample design	45
3.3	Criteria for the selection of patients	45
3.4	Collection and maintenance of patients database	46
3.5	Selection of Trial Medicine	46
	3.5.1 Pre-clinical analysis of Trial Medicine	46
3.6	Investigations	47
3.7	Outcome of the study	47
IV	RESULTS AND OBSERVATION	49
V	DISCUSSIONS	83
VI	SUMMARY	89
VII	CONCLUSION	91
	ANNEXURES	
	ANNEXURE I- Preparation of Trial Medicine	i
	ANNEXURE II – Biochemical Analysis	v
	ANNEXURE III- Physiochemical Analysis	vii
	ANNEXURE IV – Pharmacological Analysis	viii
	ANNEXURE V – Microbiological Analysis	xvii
	ANNEXURE VI – Scan Reports and Stone Analysis	xxi
	ANNEXURE VII - Proforma	xxxii
	BIBLIOGRAPHY	

LIST OF TABLES

Sl No	Name of the Tables	Page No
1	Age (Kalam) Distribution	50
2	Gender Distribution	51
3	Occupational Status	52
4	Dietary Habits	53
5	Marital Status	54
6	Personal Habits	55
7	Paruvakalam (Season)	56
8	Thinai (Land)	57
9	Thegathathuvam (Thegi)	58
10	Manothathuvam (Gunam)	59
11	Uyir Thathukal	
	a) Derangement of Vatham	60
	b) Derangement of Pitham	61
	c) Derangement of Kabam	62
12	Udal Thathukal	63
13	Kosangal	64
14	14 Vegangal	65
15	Envagai Thervugal	66
16	Neerkuri	67
17	Neikuri	68
18	Duration of Illness	69
19	Number of Stones	70
20	Position of Stones	71
21	Size of Stones	72
22	Urolithiasis Symptoms Score	73
23	Grading outcomes of the study	74

LIST OF FIGURES

Sl No	Name of the Figures	Page No
1	Age (Kalam) Distribution	50
2	Gender Distribution	51
3	Occupational Status	52
4	Dietary Habits	53
5	Marital Status	54
6	Personal Habits	55
7	Paruvakaalam (Season)	56
8	Thinai (Land)	57
9	Thegathathuvam (Thegi)	58
10	Manothathuvam (Gunam)	59
11	Uyir Thathukal	
	a) Derangement of Vatham	60
	b) Derangement of Pitham	61
	c) Derangement of Kabam	62
12	Udal Thathukal	63
13	Kosangal	64
14	14 Vegangal	65
15	Envagai Thervugal	66
16	Neerkuri	67
17	Neikuri	68
18	Duration of Illness	69
19	Number of Stones	70
20	Position of Stones	71
21	Size of Stones	72
22	Urolithiasis Symptoms Score	73
23	Grading outcomes of the study	74

LIST OF ABBREVIATIONS

%	-	Percentage
WBC	-	White Blood Corpuscles
DC	-	Differential Count
ESR	-	Erythrocyte Sedimentation Rate
Hb	-	Haemoglobin
P	-	Polymorphs
L	-	Lymphocytes
E	-	Eosinophils
BFT	-	Before Treatment
AFT	-	After Treatment
Alb	-	Albumin
Epi.Cells	-	Epithelial Cells
RBCS	-	Red Blood Corpuscles
NAD	-	No Abnormal Deposits
mm	-	Millimeter
ATP	-	Adenosine tri Phosphate
dl	-	Decilitre
MRI	-	Magnetic Resonance Imaging.
CT	-	Computerized Tomography

ABSTRACT

KALLADAIPPU is the most common disease in our country. The evidence of the disease *KALLADAIPPU* was derived from *YUGI VAIDHIYA CHINTHAMANI* 800, by Dr.K.Anbarasu B.S.M.S (Page.No.283). The clinical features of *KALLADAIPPU* can be correlated with *UROLITHIASIS* in modern science. Urolithiasis is a term originated from three greek words “ouron” for urine, “oros” for flow, and “lithos” for stone. It is the formation of calculi which are formed or located anywhere in the urinary system (i.e kidneys, bladder, uretherae, urinary tract).

Many herbal and herbo-mineral formulations have been described in Siddha text books. One such drug *SIRU NERUNJIL KUDINEER* mentioned in the book of *GUNAPAADAM MOOLIGAI* (Page.no:597). A total of 40 patients of both sex (20 OPD and 20 IPD) were selected and administered with the clinical trial medicine “*SIRU NERUNJIL KUDINEER*” 40 ml BID at PG Department of Pothu Maruthuvam, Govt. Siddha Medical College and Hospital, Palayamkottai. The whole study period is between August 2017 and June 2018.

The clinical trial medicine was subjected to Biochemical, Physiochemical and Pharmacological studies. In clinical study 60% of out patients and 50% of In patients showed Good response. And 40% of Out patients and 50% In patients showed Moderate response. No Poor response. No Adverse reaction was found in this clinical study. The statistical analysis showed good significant value ($P < 0.0001$). The Siru Nerunjil Kudineer is safe and effective and affordable cost in the treatment of Kalladaippu Noi (Urolithiasis).

CHAPTER-I

INTRODUCTION

1.1BACK GROUND

Siddha system is a unique and historical medical system of India with strong philosophical foundation behind its medical science. It is the first system to emphasise that health and is the perfect state of physical, psychological, social and spiritual component of human being. The system strongly advocates proper food habits. If human being has any alteration in food habits, it will affect the vital elements of their body. According to Thiruvalluvar in Thirukkural says that,

“மாறுபாடில்லாத உண்டி மறுத்துண்ணின்
ஊறு பாடில்லை உயிர்க்கு”

The basic theory of Siddha system of medicine is “Food is medicine, Medicine is food”.

According to Siddha system, siddhars defined 96 principles as the constituents of the human being. In that PANCHABOOTHAM are the basic elements which are included as first section of 96 thathuvams in each and every bit of all the physical and subtle bodies i.e the human body and the universe. They are Aagayam (space), Kaal (air), Thee (fire), Neer(water), Mann(earth).

பாரப்பா பூதமைந்து மண்ணீர் தேயு
பரி வாயு வாகாய மைந்தினாலே
சேரப்பாசடமாச்சி

சதகநாடி

நோய் நாடல் நோய் முதல் நாடல் பக்கம் 5

The physiological function of the human body is mediated by VATHAM, PITHAM, KABHAM i.e three Uyir Thathukal formed by the combination of five basic elements. These elements govern the physio-biological and physio-pathological functions of our body and is responsible for all kinds of illnesses and sufferings of mankind.

VATHAM is formed by the space and air.

PITHAM is formed by the fire.

KABHAM is formed by the earth and water.

The first phase in human life is attributed to vatham, the middle phase to pitham, and the last phase to kabham.

“வாதமாய் படைத்து
பித்த வன்னியாய் காத்து
சேத்தும சீதமாய்துடைத்து”

தேரன் மருத்துவ பாரதம்

Thus the three humours are said to occupy the lower, middle and upper parts of the body respectively and maintain their integrity and function. The normal equilibrium of three humours is considered as health and its disturbance or imbalance leads to a diseased state. The Siddha medicine has been claimed to revitalize and rejuvenate the metabolic dysfunctions in organs than cause the disease and maintains the bio-regulating factors namely Vatham, Pitham, Kabham.

The seven physical constituents UDAL THATHUKAL such as Saaram(plasma), Seneer(blood), Oon(muscle), Kozhuppu(adipose tissue), Enbu (bone), Moolai(bone marrow), Sukkilam(semen).

In diagnosis, examination of eight items is required which is commonly known as “EN VAGAI THERUVUGAL”

- | | |
|--------------------|---------------------|
| ➤ Naadi - Pulse | ➤ Niram - Colour |
| ➤ Sparisam - Touch | ➤ Vizhi - Eyes |
| ➤ Naa - Tongue | ➤ Maalam - Stools |
| ➤ Mozhi - Voice | ➤ Moothiram - Urine |

Siddhars are the spiritual scientists and they have classified diseases into 4448 numbers. One among them clinical entity is “KALLADAIPPU NOI”. Similarly in modern medicine it is compared to “UROLITHIASIS”.

In *yugi vaidhiya chinthamani*- 800, urological disorders are classified into two categories such as

- 1) Neerina perukkal noi – where the urination will be excess .
- 2) Neerina arukkal noi – where the urine output will be reduced .

The disease KALLADAIPPU is placed under Neerina Arukkal noi. One of the works of yugi munivar, Kalladaippu is dealt under the chapter **KALLADAIPPU ROGAM NITHANAM**. Yugi documented the sequential order of dissemination of knowledge of Kalladaippu from lord shiva to till yugi for the benefit of the people living in the world.

Urolithiasis is the process of forming stones in the kidneys, bladder, and or urethrae. It is the most common disease of present society due to modern life style, abnormal diet habits, and low fluid intake. The disease is denoted by the sudden obstruction of the urinary tract, while passing urine by excretion there is presence of small sand like granules. The diagnosis of calculi can be confirmed by ultra sound examination, urine & blood test are also commonly performed.

The efficacy of invasive therapies such as extra corporal shock wave lithotripsy and ureteroscopy has been proven by several studies. However, these techniques are not risk free and they are problematic and quite expensive and complications.

Several drugs and medicines are available for treating KALLADAIPPU NOI. However, clinical trials on the treatment of Kalladaippu noi have not yet been undertaken the medicine “SIRU NERUNJIL KUDINEER” (Internal), it has to mention in *GUNAPAADAM MOOLIGAI* (Pg.no.597) text book. It is well known for its diuretic and lithotriptic action in treating the disease KALLADAIPPU. So I have chosen this medicine for my dissertation work.

1.2 AIM AND OBJECTIVES:

AIM OF STUDY:

To pre-clinical, clinical study about Siddha formulations of “SIRUNERUNJIL KUDINEER” in the management of “KALLADAIPPU NOI” (urolithiasis).

OBJECTIVES:

1. To collect the various literary evidence for Kalladaippu disease.
2. To study the Siddha formulation of the drug SIRU NERUNJIL KUDINEER in the treatment of KALLADAIPPU (UROLITHIASIS) for the clearance / reduction in the size of the calculus and clinical symptoms.
3. To collect about the disease Kalladaippu noi with deep observation of aetiology, clinical features mentioned in various Siddha literatures and also in modern text books, diagnosis and prognosis.
4. To confirm the diagnosis in Siddha system with the help of modern parameters during and after treatment in all patients.
5. To perform urine analysis, haematological studies and ultrasonography for all patients.
6. To perform stone analysis in selected cases.
7. To undertake biochemical physiochemical microbial analysis of the clinical trial drug.
8. To evaluate pharmacological activity of my trial drug SIRU NERUNJIL KUDINEER.
9. To assess the safety profile of the trial drug.

CHAPTER-II

REVIEW LITERATURE

2.1 SIDDHA ASPECT

Siddha system of medicine is an old age traditional system with unique properties is not only treating a disease but gives us an immense perception and approach to lead a healthy life. Among the various diseases, “Kalladaippu Noi” is one of the most common diseases. Several preventive and causative treatments are found in various siddha literatures for Kalladaippu Noi.

In Siddha literature, Kalladaippu noi is mentioned by Yugi Munivar in “*Yugi Vaidhya Chinthamani 800*”. It is one of the urinary disease which come under Neerinai Arukkal Noigal.

“நீரிரு வினைக் குணத்தை
நீயறி விரித்துச் சொல்வோம்
நீரினை பெருக்கலொன்றே
நீரினை யருக்க லொன்றே
நீரிழிவுடனே கொல்லும்
நீர்க்கட்டு வினைகளொன்று”

தேரன் கரிசல்

நோய்நாடல் நோய் முதல் நாடல் - 2ம் பாகம், பக்கம் 420

2.1.1 வேறுபெயர்கள் (SYNONYM)

ASHMARI ROGAM

2.1.2 இயல் (DEFINITION)

kalladaippu noi is defined by various authors,

a) In “Agathiyar Gunavagadam”, kalladaippu noi is defined as below:

“தானென்ற மூத்திரத்தில் நற நறவென்று
தங்கியதோர் பொடியெனும் மணல்தானப்பா

வானென்ற சிறியதொரு கல்லாவதப்பா
 வளமாக வந்துவிழும் நோய்க்கு தானே
 ஏனென்ற அஸ்மரி ரோகமென்ற பேராம்
 எளிதாகக் கல்லுகள்தான் விழுகும்போது
 கோனென்ற குண்டிக்காய் மூத்திரக்குழல்பா
 குணமான மூத்திரப்பை நீர்த்தாரைக் கேளே”
 கேளடா முன் குறியில் எரிச்சல் கண்டு
 கெடியாக வேதனைகள் காட்டுமப்பா
 வாளடா சிறியதொரு கற்கள்தானே
 வளமான மூத்திரப்பை குழல் வழிப்படியாய்த்
 தேளடா வரும்போது திரேகந்தன்னில்
 தெரிப்பது போல யிருவேதனை செய்யும்பாரு
 நாளடா கற்கள்தா நிறங்கிவிட்டால்
 நலமான வேதனைகள்தான் தீரும்பாரே”

அகத்தியர் குணவாகடம் பக்கம்.6

According to Agathiyar, Kalladaippu noi defines as “Deposition of crystals which look like sand followed by small size of stones which is excreted in the urine. Sometimes the stones obstruct in the kidney ureter, urinary bladder and urethra. When the stones reaching the urethral orifice, intense burning sensation in the genital area. Then the stones get expelled and pain is relieved.

b) In “Jeeva Ratchamirtham”

Kalladaippu noi is defined as pain present in abdominal region particularly around the umbilicus, fever, dysuria, urine smell like that of goat urine, chills, anorexia are common features of this disease.

c) In “T.V.Sambasivam Pillai Agarathi”

Large concentration of stones in the bladder or Kidney produces calculus or gravel. It causes difficulty in passing urine.

d) In “Siddha Maruthuvam”

Sudden obstruction of flow of urine during micturition, pain in the tip of the penis in males and clitoris in females burning sensation in urethral orifice, pain

radiating from loin to groin, presence of sand like stones in the urine are the symptoms of this disease.

2.1.3 நோய் வரும் வழி (AETIOLOGY)

a) According to Maanmurugiyam are mentioned as,

கருநீரடக்கல் விரையில் அடிபடல்
நீரியந்தாக்கல் சிறு நீரடக்கல்
வளிநோய்மிருக்கு முணவும் ஒழுக்கமும்
கடைப்பிடித்திடுதல் மேகமுதற் பல
பிணியுறல் எழுமுவை யடிப்படையாகக்
கல்லடைப்புயென்னும் கடும்பிணி விளையும்
வளியது மீறியோடு மல்லாது
கருநீரோடுங் கலந்து நீரகத்துச்
சிறுநீர்க் கழிவு தொடுத்தாலும்
அன்னவை கல்லெனத் திரளுமென்ப

பக்கம்.118

The above poem described as,

- Trauma on testies, suppression of urine & semen
- Derangement of humour in blood.
- Excessive indulgence in sexual activity.
- Inflammation of bladder.
- Syphilis, stagnation of urine in urinary tract.
- Dryness of semen causes formation of stones.
- Increased intake of food that cause flatulence.

b) According to Siddha Maruthuvanga Churukkam.

“நீரினைத்தடுத்தல் செய்யின்
நீர்க்கட்டுத் துவாரம் புண்ணாம்
பாரிடுஞ் சந்து சந்தில்
பண்புறு நோவதாகும்
நேரிலங் கயருங் காமியம்
நிச்சயநோதல் செய்யும்
பாரினி லாபான வாயு
பண்புறச் சேருமன்றே”

பக்கம் 212

The above poem said when urine is ceased deliberately, obstruction of urine flow, ulcer in the urethral orifice, pain in the glans penis, increased abaana vayu in the abdomen, it leads to

“சுக்கிலந்தனைய டக்கின்

சுரமுடனீர்க்கட் டாகும்

பக்கமாங்கைகால் சந்து

பார நோய் வழியிறங்கும்

மிக்கமார் நோயுண்டாகும்

மிகுத்திடும் பிரமே கந்தான்

தக்க தோர் போதுமாகின்

தரித்திடும் வாயுக் கூறே”

பக்கம் - 212

The natural urges of human beings, semen needs to be discharged regularly. The above poem said emphasizes that deliberate cessation of seminal discharge results in fever, lumbar pain, oliguria, and white discharge.

c) According to Yugi Vaidhya Chinthamani 800

“தெளிந்ததோர் கல்லடைப்பு உற்பத்தி கேளாய்

சிறிதுநாட் டொடங்கியே மேகந் தன்னில்

தளிந்ததோர் சலப்பையி லுதிரத் தோய்ந்து

சந்தசத் தாகவே பருத்துக் கொள்ளும்

வளிந்ததோர் வாதபித்தங் கோபித் தக்கால்

வந்துபெருங் கல்லாய் நீர் வழிய டைத்து

நளிந்தோர் நாலுவிதக் கல்ல டைத்து நண்பான

வரலாறு நாட்டக் கேளே”

பாடல் 725, பக்கம் 283

“கலங்கினதோர் தண்ணீர்தான் குடித்த பேர்க்குங்

கல்லெலும்பு மயிர்மண்தான் கலந்தன் னத்தில்

அலங்கினதோ ரன்னங்க ளருந்த லாலும்

அழுகலோடு முத்தபண்ட மருந்த லாலும்

மலங்கினதோர் மாப்பண்ட மருந்த லாலும்

மந்தத்தில் வாய்வான பதார்த்தந் தன்னை

துலங்கினதோர் ருசிதன்னிற் சுவைத்த லாலும்

சுருக்காய்க்கல் லடைப்புவந்து தோன்றுந் தானே”

பாடல் 727 பக்கம் 283

In Chronic (syphilitic disease) Mega Noi the semen will stagnate for a long time in the urinary tract so it will obstruct the urinary flow so urinary constituents will easily deposit on the urinary tract and form the stone. At that time due, to increased Vatham and Pitham humour, the small stones becomes larger in size and block the urinary passage.

2.1.4 பொதுகுறி குணங்கள்(COMMON SYMPTOMS)

உந்தி தன்னினும் அதன் கீழ் மருங்கினும்
விரைநரம் பிடித்தும் நோவு தோன்றல்
சிறுநீர் நெறியில் கல்லுரத்தடுப்பின்
முரித்து முரித்து நீர் வீழ்ந்திடுதல்
கல்லது விலகி நின்றிடின சிறுநீர்
தெளிந்தின மஞ்சள் நிறத்தி லொழுதல்
எனுமவை கல்லடை பொதுகுறி யென்ப

நோய் நாடல் நோய்முதல் நாடல் முதல்பாகம் பக்கம் 427

- Gradual or sudden obstruction of flow of urine
- unbearable pain (i.e agonizing pain) in the penis
- Burning and scanty micturition and Haematuria
- Colicky pain radiating from loin to groin region, lower abdomen, urethra & genitalia if the calculus is irregular in shape.

2.1.5வகைகள் - (CLASSIFICATION)

A) In “Yugi vaidhya chinthamani 800”

“தோன்றிடதோர் நாலினிட நாமங்கே ளாய்
சுறுக்கான வாதத்தின் கல்ல டைப்பு
பூன்றியதோர் பித்தத்தின் கல்ல டைப்பு
புரண்டதோர் சிலேட்டுமத்தின் கல்ல டைப்பு
தீன்றியதோர் தொந்தமாங் கல்ல டைப்பு
தேகத்தைப் பற்றியே சிறிது காலம்
தான்றியே சலப்பையில் வந்தி ழிந்து
சருவியே லிங்கத்திற் றரிக்குந் தானே”

பாடல் 728, பக்கம் 284

The above poem mentioned, that Kalladaippu noi is classified into four types.

They are:

1. Vali Kalladaippu
2. Azhal Kalladaippu
3. Iyya Kalladaippu
4. Mukkutra Kalladaippu

Vali Kalladaippu:

“தரித்து நாயிக்கு சுருக்கமாய் குற்றிச்
சலமலந்தான் வீழாமற் றம்ப மாகி
வரித்துமே லிங்கத்தில் வலியு மாகி
மருவியதோர் பொத்தியெலாஞ் சுரந்து கட்டி
திரித்தியே கிடைக்கொடாப் பிரட்டலாகித்
தேம்பியே மூச்சமாய் வயிறு முப்பும்
உரித்ததோர் சதைபோல உவர்ப்பு மாகும்
ஓங்கியதோர் வாதக்கல்ல டைப்பு தானே”

பாடல் 729, பக்கம் 284

Acute pain felt just below the umbilical region and penis. Scanty micturition obstruction of urine flow. Sometimes mucous discharge in urine, patient unable to sit.

Azhal Kalladaippu

“அடைப்பாகிச் சலந்தானு மருவ லாகி
அயங்காச்சிச் சொருகினாற் போலே காணும்
புடைப்பாகப் பொற்றியெங் கும்பு முக்கமாகிப்
பூட்டுப்போல் பிகுவாகிப் பிரட்ட லாகும்
மடைப்பாகி உதிரநிற மாயக்கல் லாகி
வந்தழிந்து லிங்கத்தில் மாட்டிக கொள்ளும்
குடைப்பாகிக் குற்றலாய்க் கூச்சலாகிக்
குதட்டுமே பித்தக்கல் லடைப்பு தானே”

பாடல் 730, பக்கம் 285

It is characterized by reduced urine output with characteristic burning sensation (similar to introducing a root hot iron needle into the urethra) Excretion of small blood stained stones. Causing pricking pain & tenderness.

Iyya Kalladaippu

“தானா தொப்புளிலே வில்லு போலச்
சலியாமற் சுரந்துமே சற்றே குற்றும்
ஏனான காலோடு கைகள் சந்து
இடுப்புதான் குடைச்சலா யிசிவு காணும் வேனான
லிங்கத்தின் வெண்மை தன்னில்
விறவிநென் நேகடுப்பாகி வியர்வையாகும் தேனான
வெளுப்புக்கல் சிறுகல் லாகிச்
சிக்கலாய் வந்திறங்குஞ் சேட்பந் தானே”

பாடல் 731 பக்கம் 285

It is characterized by excruciating pain in the umbilical region. Pain in the joints of upper and lower extremities. profuse sweating and expulsion of small white coloured stones in the urine.

Mukkuutra Kalladaippu

“வந்திறங்கும் நீர்த்தாரை யடியிற் றானும்
மாவருத்த முண்டாகி வலியு மாகி
நொந்திறங்கி நீர்தானு மருவி பாயும்
நொயதான சிறுமணல் போல் நொறுங்கி கல்லான்
சந்திரங்கி நீர்வழியில் வந்து வீழும்
தாக்கான சிறங்கைக்கல் தினமொன் றுக்கு
துந்திறங்கித் தினந்தினமு மிழந்து கொல்லும்
தொந்தமாங்க லடைப்புச் சூட்டிட் டாயே

பாடல் 732, பக்கம் 286

Severe pain felt below the urethral region. Irregular urine output. It is characterized by disintegration of stones into small like granules excreted in the urine and semen.

B) In “Noi Vilakkam”

வளிமுதல் முன்றினுந் தோன்ற லாலும்
கருநீர் தன்னிற் தோன்ற லாலும்
கல்லடை நால்வகைப் படுமென மொழிப

According to Noi Vilakkam, Kalladaippu Noi is classified into 4 types.

1. Vali Kalladaippu
2. Azhal Kalladaippu
3. Iyya Kalladaippu
4. Karuneer Kalladaippu

வளிக்கல்லடைப்பு குறிகுணங்கள்:

படர்மிகப் படுத்தல் பற்கள் கடித்தல்
நடுங்கல் உந்தியும் குறியும் பிசைதல்
கசடுகீழ் சளியொடு கழலல் அழுதல்
சிறுநீர் துளித்தல் என்பவும் பிறவும்
வளியின் கல்லடைக் குறியென மொழிய
கறுத்துஞ் சிவந்தும் முனைகள் பரந்தும்
வளியின் கல்லது வடிவனு மென்ப

-நோய் விளக்கம்

- Tongue biting, palpitation and chills.
- Lower abdominal colic and pain in the external genitalia.
- Dribbling of Urine, The Stones are blackish red in colour.

அழல்கல்லடைப்பு குறிகுணங்கள்:

“சுட்டென நீரியம் மிகவெப் பிடுத்தலும்
நோதலும் அனலக் கல்லடைக் குறியே
சிவந்தும் கறுத்து மஞ்ச ளாகியும்
சேங்குரு வடிவில் கல்லது தோன்றும்”

-நோய் விளக்கம்

- Burning micturition, Dysuria
- Passing reddish black or yellow coloured stones

ஐயக்கல்லடைப்பு குறிகுணங்கள்:

“நீரியங் குத்தல் திணித்தல் குளித்தல்
எனுமவை ஐயக் கல்லடைக்குறியே
வெளுத்தும் தேனிற மாகியு மொளிர்ந்தும்
பெருவடி வுடைத்தாம் ஐயக் கல்லடை”

-நோய் விளக்கம்

- Pricking pain with severe intensity while passing urine.
- Fever with rigors
- White or honey coloured shining or luminant large size stone expelled.

கருநீர்க்கல்லடைப்பு குறிகுணங்கள்:

“நீரியம் நோதல் சிறுநீர் தடைப்படல்
விரைவில் கிடுதல் எனுமவை பிறவும்
கருநீர்க் கல்லடைக் குறியெனமொழிப”

-நோய் விளக்கம்

- Sudden or gradual obstruction to flow of urine
- Excessive Vali kutram breaks the stones into small and large size crystals and expels along with urine, Sudden stoppage of urine stream
- Retention of urine, Abdominal pain, Loss of taste, excessive thirst.

C) In “Dhanvanthiri Vaithyam II – Part”

1. Kallarippan
2. Pitha ashmari
3. Silethuma ashmari
4. Sukkila ashmari

Page 9 & 10

Kallarippan:

“சுத்துநீர் நாளந்தன்னீர் சுக்கிலந்தன்னீர் சிலேற்பனம்பித்தமீ
துலர்த்தல் கல்லாய் பீசுகிநீ டைத்துக் கொள்ளுங் கொத்துநீ
ரிற்றுவிழுங் கொப்புள்ளோ குடம்பு காயுஞ் சித்தா யருசி
யுண்டாஞ் சேர்ந்தகல் லெரிப்பானாமே”

It is learnt from this poem that when kabam and pitham increase, urine and semen dry up, resulting in the formation of stone which in turn lead to obstruction of urinary tract, dysuria, pricking pain in umbilicus, fever and anorexia.

Silethuma ashmari:

“நீர் வரு தாளத் தன்னில் நின்றுநீர்
சிறுத்துக்கொண்டுசோர்ந்தரும் சிவப்பு வெண்மை சுக்கிலம்
போல வீழும் பேர்பெற நாலாமெட்டும் பின்னமாய் கல்லு
வீழும் ஏர்பெறு சிலேற்பனத்தில் அச்மரி என்னலாமே”

This poem states that when the calculus arrive the urethral orifice, the volume of urine gets reduced gradually, leading to Oliguria. Ultimately, the stone is broken into four to eight pieces and pass through the urine.

Pitha ashmari:

“பெய்யும்நீர் நாளத் தன்னில் பித்தத்தா லெரிப் பெழுந்துசெய்யுவுஷ்
ணத்தால்வெந்து சேங்கொட்டை போற்கல் லுண்டாம் நய்யவே
தனைகள் செய்யும் நவில் குணம் பித்தந்தன்னில் எய்தசு
மரியென்றெழுன் னியம்பின ரறிவின் மிக்கொர்”

It is evident from this poem that when pitham accumulates in the urethral orifice, severe pain will result in along with burning sensation.

Sukkila ashmari:

“சுக்கிலம் வருங்காலத்தில் தம்பித்தாற் சுக்கிலந்தான்
மிக்ககல் லாகிவெம்பி விதனமாய் நீர்விடாமற்
சிக்கிநீர் விழா மலங்கே மணல் விழும் வெளுக்குந்தேகம்
மிக்குணஞ் சுக்கிலாசு மரியசாத் தியமென்றோதே”

If semen discharge is ceased it gets concentrated and dried up in the uretero-vesical junction, preventing the flow of urine which results in anuria. Under this condition sand grains like stones pass through the urine and anemia occur.

D) In “siddhar Aruvai Maruthuvam”

Kalladaippu noi is classified into four types.

1. Vali kalladaippu

2. Azhal kalladaippu
3. Iyya kalladaippu
4. Veneer or Manal kalladaippu

Page-112

E) In “Roga Nirnaya Saaram under Roga Nithanam”

Ashmari rogam is classified into five types:

1. Vatha kalladaippu
2. Pitha kalladaippu
3. Kapha kalladaippu
4. Sukkila kalladaippu
5. Swargara Ashmari or Kalladaippu rogam.

Page-79,80

1. Vatha ashmari

Urine turns to black in colour, dribbling, grunting teeth and rubbing of penis.

2. Pitha ashmari

Tip of penis turns to black in colour and urine turning to red, white and yellow in colour

3. Kapha ashmari

Urine becomes white in colour and highly viscous and flows down like honey.

4. Sukkila ashmari

Cessation of seminal fluid discharge during sexual intercourse leads to retention of semen in vas deferens or spermatic cord, which get dripped up by vatham. This condition eventually results in inflammation of testis and lower abdominal pain.

5. Swargara ashmari or kalladaippu rogam

Semen is retained in the spermatic region and gets dried up. The dried semen turns to stones in the size of sand, green gram, ground nut and get mixed up with urine and pass through the urethral orifice.

F) In “Anubhava vaidhiya Devaragasiyam – I Part”

1. Vatha ashmari
2. Pitha ashmari
3. Kapha ashmari
4. Sukkila ashmari
5. Swargara ashmari or kalladaippu rogam

Page-131

G) In “sikitcha rathna deepam – Vaidhya Chinthamani – II part”

1. Vatha kalladaippu
2. Pitha kalladaippu
3. Kapha kalladaippu
4. Mukkutra Kalladaippu

Page-140&141

1.Vatha kalladaippu

The symptoms include acute pricking pain in the lower abdomen, obstruction of the flow of urine, scanty micturition, pain in the penis, making the patient unable to sit, crying, flatulence, presence of albumin in the urine and mucous discharge with urine.

2.Pitha kalladaippu

The symptoms are obstruction of the flow of urine, burning sensation in the urethral orifice (the burning sensation refers to melting point of iron put on the external meatus), acute pain in the urethra and expulsion the small blood stained stones.

3.Kapha kalladaippu

In this kalladaippu, patient suffers from severe pain in the lower abdomen, pain radiating towards the thigh, joint pain associated with rigor and pain in the tip of glans penis. Finally, small white coloured stones are expelled along with urine.

4.Mukkuutra kalladaippu

Pain in the urethral orifice, pain during micturition, presence of small sand grain like stones in urine are the cardinal features of mukkuutra kalladaippu.

2.1.6 SOME DISEASES ASSOCIATED WITH KALLADAIPPU NOI IN SIDDHA TEXT:

உக்கார சூலை (UKKARU SOOLAI)

“குத்து முத்காரசூலை யின்கு ணந்தான்
கோர்வையாய் விலாவுதனில் முதுகில் நெஞ்சில்
அத்தி யினில் நாபியில பானமாங்கு தத்தில்
அதிக துன்மாங்கிசந்தான் வளர்ந்து மேவிப்
பத்துமணற் படுக்கைபோற் சலத்து வாரப்
பதிநெருக்கி முத்திரமாங் கிரிச்சி யுண்டாய்த்
தத்துசடங் கடுப்பெடுத்து மதிக லங்கித்
தளர்ச்சி யொடுமயக்கமாய்த் தள்ளுந் தானே”

- யூகி வைத்திய சிந்தாமணி – 800 பாடல் 233, பக்கம் 88

Excessive growth of muscles in chest region, back of trunk, umbilicus, anal and urethral orifice followed by stricture of urethral orifice by sand like crystals blocked in urethra causes dysuria, tiredness, body pain occurs.

2.1.7 முக்குற்ற வேறுபாடுகள் : (PATHOLOGY)

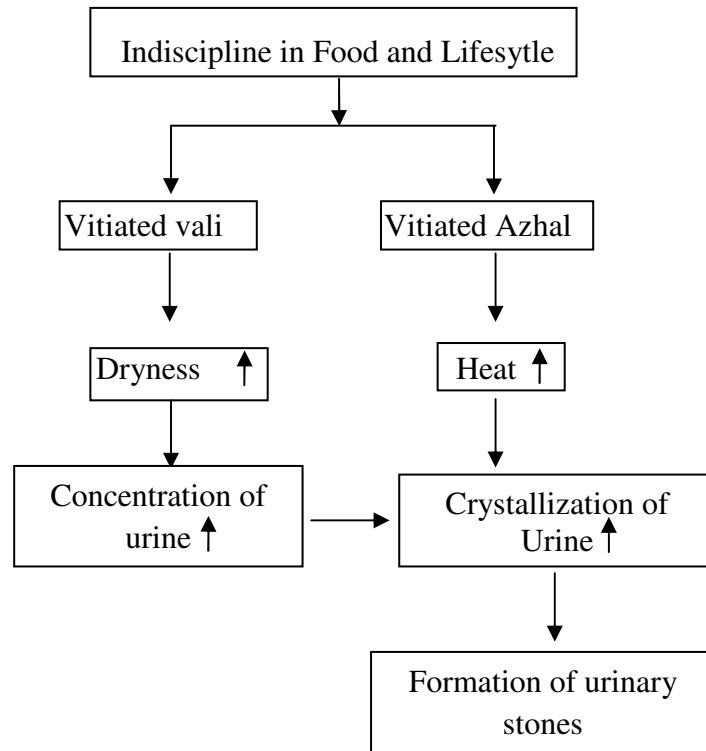
“வாயுவினால் மலம் சலங்கட்டிடும்
பிரித்திடும் பித்தம் பேரஞ் சலத்தினாலே”

சித்த மருத்துவாங்க சுருக்கம் பக்கம் - 154

Alteration in diet and lifestyle causes the vitiation of the vatha humour for sufficiently enough time, which can further cause the imbalance in either of the other two humours and hence pitham is also deranged resulting in urolithiasis. Vali is responsible for dryness and Azhal is responsible for the heat. This causes decrease in body fluids and increase in concentration of urine and thereby the crystal grows and aggregation takes place in the urinary passage. As (kezhnökkukal) “Abanan” one of the component of ten vayu, is strongly responsible to expel the deposits that will be

automatically washed out in urine. If Abanan is not strong enough, the deposited material will not be expelled and pave way for renal stones.

SIDDHA PATHOLOGY & SCIENTIFIC ASPECTS OF KALLADAIPPU



More over Vatham is responsible for maintenance of 14 reflexes including micturition. Therefore body pain, pricking pain in external genitalia and constipation seen in urolithiasis (Kalladaippu) due to altered vatham humour.

Pitham has direct link with urine (i.e) “Pitham Siruneeril Adangum”. Therefore symptoms of darkened yellow urine, sometimes reddened urine seen in Kalladaippu due to elevated pitham humour.

Decreased Kapham humour prones the body constitution to dryness and heat.

All these derangements create the alterations in biochemical parameters of Kidney function form the symptoms of urolithiasis.

2.1.8 PRINCIPLES OF SIDDHA DIAGNOSIS IN UROLITHIASIS:

Siddhars investigate the cause of the disease the signs and symptoms, complications if any and anatomical (udal kooru) changes to arrive at a diagnosis of a disease. They examine both the body and the disease together to arrive a conclusion regarding the condition or diseases.

They followed two paths called “Noi naadal” in simple terms defined as the approach to the disease and “Noi Mudhal Naadal” which is determination of aetiology of the disease. These diagnostic tools designed by siddhars that they can also determine the risk factor and help in early prediction of the illness. The following are the diagnostic methodologies of urolithiasis in Siddha.

S.No.	Thathuvams	Affected basic principle	Symptoms of Kalladaippu
1.	Uyir thathukkal (3)	1. Vatham (10) Abanan Udhanan	Scanty micturition, Haematuria, Dysuria, Nausea and vomiting
		2. Pitham (5) Saathagapitham	Dysuria, oliguria
		3. Kabham (5) Santhigam	pain present in the joints
2.	Udal thathukkal (7)	1. Moolai (bone marrow) increased	oliguria
		2. Sukkilam (semen) increased	renal calculus
3.	Iymboothangal (5)	1. Vayu (Air)	obstruction in genitalis
		2. Thaeyu (fire)	Dryness, heat burning sensation
		3. Appu (water)	reddened urine
4.	Iymporial / Iyampulangal (5)	1. Mei	koocherithal
5.	Kanmenthiriyam / Kanmavidayam (5)	1. Eruvai	constipation

6.	Aasayam (5)	1. Salavasayam	oliguria
		2. Sukkilavasayam	pain and burning sensation in external genitalis
7.	Yakkai (3) (General characters)	1. Vatham	“Siruneer porumi Kaduthu vizhum”
		2. Pitham	“Neerum uyarntu sivappagum”
8.	Manikkadai	1. 9 ¼	“Neer kaduthu siruthu irangam”. dysuria and stranguria
		2. 6 ¾	proned to urolithiasis in 3years of time
9.	Thinai (5)	1. Muthuvenil 2. Karkalam	Affected
10.	Kaalam (7)	1. Neithal 2. Mullai	Affected

2.1.9 நோய் கணிப்பு முறை (DIAGNOSIS AND PROGNOSIS)

The Diagnostic methodology in siddha system is unique and it is made purely on the basis of clinical acumen of the physician. In “Piniyari muraimai” the following principles are

1. Poriyaal arithal - Physical examination
2. Pulanaal arithal - Clinical examination
3. Vinaathal - Medical History

1. PORIYAAL ARITHAL : It means understanding by the five organs of perception.

- Mei – oor (somatic sense) to feel all types of sensation
- Vai - suvai (taste) for knowing taste.
- Kan - oli (vision) for vision
- Mookku - Natram (smell) for knowing the smell
- Sevi - osai (sound) for hearing

2. PULANAAL ARITHAL : It means understanding by sensing the objections.

Kai	-	All Manocurves
Kal	-	Walking
Vai	-	speaking
Eruvai	-	Defecation
Karuvai	-	Reproduction

3. VINAATHAL (Interrogation)

The first step in diagnosing a disease by knows their personal history of the patient through Interrogation. The physician should interrogate the patients name, age, native place, socio economic states, food habits, personal habits, present complaints, of history of present illness, history of past illness, through this applied eight tools of investigation (i.e) “Envagai Thervugal”.

2.1.10 எண்வகைத் தேர்வுகள்:

“அகத்துறு நோயை கரத்தாம லகம்போல்
பகுத்தறிவீர் நாடிப் பரிசம் - தொகுத்த நிறம்
கட்டுவகைச் சொல்மொழி கண்ட மல முத்திரம் நா
எட்டுவகை யாலு மறிவீர்”

-அகத்தியர் வைத்திய சிந்தாமணி வெண்பா 4000

“நாடி பரிசம் நாநிறம் மொழிவிழி
மலம் முத்திரமிவை மருத்துவராயுதம்”

-தேரையர்

“மெய்குறி நிறந்தொனி விழிநாவிருமலம் கைக்குறி”

-தேரையர்

According to Agathiyar vaithiya chinthamani venba 4000 and saint therayar, the Envagai Thervugal (Eight types of diagnostics) include, Naadi(pulse), Naa (tongue), Niram(colour), Mozhi(voice), Vizhi(eyes), Maalam(faeces), Neer(urine) and Sparisam (touch & palpation).

In “Gunavagada Naadi” about the Envagai Thervugal as following.

“தரணியுள்ள வியாதி தன்னை யட்டாங்கத்தால்
தானியறிய வேண்டுவது யேதோ வென்னில்
திணியதோர் நாடிகண்கள் சத்தத்தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
யிரணமல மூத்தரமாவைக ளெட்டும்
யிதம்படவேதான் பார்த்து குறிப்புங்கண்டு
பரணருளால் பெரியோர்கள் பாதம் போற்றி
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே”

பக்கம் - 129

In “Agathiyar vaithya vallathy” to apply the envagai thervugal for diagnosis of the disease.

“தொகுக்கலுற்ற அட்டவித பரீட்சை தன்னை
துலக்கமுறும் பண்டிதரே தெளிவதாகப்
படுக்கரிய நாடியை நீ பிடித்துப்பாரு
பகர்கின்ற வார்த்தையைப் பார் நாவை பாரு
வகுக்கரிய தேகமென தொட்டுப் பாரு
வளமான சரீரத்தின் நிறத்தைப் பாரு
சகிக்கரிய மலத்தைப் பாரு சலத்தைப் பாரு
சார்ந்த விழிதனைப் பார்த்து தெளிவாய் காணே
நீடிய விழியினாலும் நின்ற நாக்குறிப்பினாலும்
வாடிய மேனியினாலும் மலமொடு நீரினாலும்
சூடிய வியாதி தன்னைச் சுகம்பெற அறிந்து சொல்லே”

அகத்தியர் வைத்திய வல்லாதி

1. Naadi (pulse)

Naadi is nothing but the manifestation of the vital energy that sustains the life within our body. It plays an important role in “Envagai Theruvugal” and it has been considered as foremost thing in assessing the prognosis and diagnosis of various disease. Any variations occurs in three humours it is reflected in naadi. These three humours organize, regularize and integrate basic functions of the human body. So, Naadi serves as a good indicator of all ailments.

“விழுகும் சிலநேரம் விடுபட்டு நீரோடும்
ஒழுகிய வாயுவும் ஒதுங்கினால் நோகாது
வழுகிய மந்தத்தால் வாயுவந்தே புகில்
கழுமி முதிர்ந்திடும் கல்லெரிப்பு ஆகுமே”

திருமூலர் கருக்கிடைவைத்தியம் 600

The above line mentioned that the Vatham and Mantham combined together, Kalladaippu noi may occur.

“அறைந்தோம்வாத ரோகியுடல்
அழறக்ண்முகமும் பல்மலமும்
நிறைந்த விழியில் நீர் வடியும்
நீண்ட நாவு கறுத்திடவும்
திறைந்தமுள்ளாய் தானிருக்குஞ்
சிறு நீர் பொருமி கடுத்து வரும்
உறைந்த நீருங்கருகருத்து
முறையாய் ரோகமு முண்டாமே”

அகத்தியர் நாடி

நோய் நாடல் நோய் முதல் நாடல் திரட்டு- முதல் பாகம், பக்கம் - 165

“மேவியவாதஞ் செய்யும்
குணந்தனை விரும்பிக்கேளு
தாவிய வயிறு மந்தஞ்சந்துகால் பொருத்து நோவாம்
சேவிய தாது நாசஞ்
சிறுத்துடன் சிறு நீர்வீழும்
காவியங் கண்ணினாளே
மலமது கருகிக் காணும்”

இரத்தின சுருக்க நாடி

The above two poems describes that aggravation of Vatham naadi produces symptoms of Kalladaippu noi.

“எண்ணிய வாதமொன்றும் பித்தமிரண் டெழுந்தாகில்புண்ணென
யுடம்பு நோவாம் புகையெழ யெரியும் நெஞ்சு திண்ணமாய்

நாவரண்டு சிறுத்துநீர்க் கடுத்து விழும் அண்ணவார்
உரைந்தவுண்மை யாயுரு தேவன்தானே”

தன்வந்திரி வைத்தியம் - முதல் பாகம், பக்கம் 11

The above line mentioned when Vatham and Pitham combined together which may result in Kalladaippu noi.

2. Sparism (Touch)

In Sparism the temperature of skin (Thatpam-cold or veppam-heat), smoothness, roughness, sweating, dryness, hard patches, chillness, greasy, swelling abnormal growth of organs and tenderness can be felt.

On examination in Kalladaippu patients tenderness over the lower abdomen, renal angle and lumbar region can be felt, sometimes swelling can be felt (may be due to hydronephrosis)

3. Naa (Tongue)

On examination the physician is expected to observe the features of the tongue and its colour, shape, size, coating, moisture, movement, ulcer, fissure, crust. In Kalladaippu noi, of the patient suffers from constipation, the tongue would seen to be coated.

In karuneer kalladaippu noi the patient has loss of taste sensation.

“கருநீரகல்லின் வளி சினந்தெழுந்து
சுவைகெடல் வெளிறு மறுப்பு நீவேட்கை”

-நோய் விளக்கம்

4. Niram (Colour)

The physician is required to observe the colour of the skin, conjunctiva, tongue, nail bed and hair etc... and make a note if any abnormal colour changes.

Vali udal	-	black colour
Azhal udal	-	yellow or red colour
Iyya udal	-	white or yellow colour

In Kalladaippu noi body complexion depends upon the body constitution, pallor of the body is observed in Sukkila ashmari.

“சிக்கிநீர் விழா மலங்கே மணல்விழும் வெளுக்குந்தேகம்
மிக்குணஞ் சுக்கிலாசு மரியசாத் தியமென்றோதோ”

தன்வந்திரி வைத்தியம் - 2 பாகம், பக்கம் 10

5. Mozhi (Speech)

By examining, the mozhi (speech) the various characters can be noted such as hoarseness, history voice, slurring speech, various disorders of speech such as dysarthria can be noted. In kalladaippu noi, there is low pitch voice due to agonizing pain of lower abdomen and burning micturition.

6. Vizhi (Eye)

On examine the colour of eye like pallour, reddish or yellowish discolouration and characters like dryness, odema, lacrimation any visual disturbances.

7. Maalam (Stools)

It is necessary to examine the nature (consistency) colour, quantity, hard stools (or) loose stools presence of blood and froth and also pain during defecation.

8. Moothiram (Urine)

Urine examination is one of the good diagnostic tool when compared to other Envagai thervugal.

“தரித்து நாபிக்கு சுருக்கமாய் குற்றிச்
சலமலந்தான் வீழாமற் றம்ப மாகி
வரித்துமே லிங்கத்தில் வலியு மாகி
மருவியதோர் பொத்தியெலாஞ் சுரந்து கட்டி
திரித்தியே கிடைக்கொடாப் பிரட்டலாகித்
தேம்பியே மூச்சுமாய் வயிறு முப்பும்
உரித்ததோர் சதைபோல உவர்ப்பு மாகும்
ஓங்கியதோர் வாதக்கல்ல டைப்பு தானே”

பா 729, பக்கம் 284

In Kalladaippu Noi, urine was in high concentrate and sometimes it contains blood stains (Haematuria). Patient having loin to groin pain and burning pain with glans penis while passing urine or end of the urine. Sometimes patients having severe abdominal pain, urine is bitter taste or aromatic odour in nature.

நீக்குறிப்பு சிறப்பு:

“தர்க்கசாத்தி திரிக ளானோர்
தங்களிற் றேர்ந்து நாடி
வர்க்கமாம் நாடி தன்னில்
வருவது மயக்கம் மென்றே
உற்றநீர்ப் பரீஷை பாய்ந்தே
யுரைத்தன ரிதற்கு நேராய்
மற்றொரு விதிநூ லில்லை
மருத்துவ கலைவல்லோர்க்கே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 568

In order to sheet off the ambiguity in the diagnosis of disease through pulse perception. The exponent have charted out a method called Neerikuri – an in camparable method of diagnosis.

சிறுநீரின் பொதுகுணம் :

“வந்தநீருக் கரியெடை மணம் நுரை எஞ்சலேன்
றைந்திய லுளுவை யறைகுது முறையே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 510

The above line mentioned that the five parameters should be examined in each urine sample.

1. Niram (Colour)
2. Edai (specific gravity)
3. Nurai (froth)
4. Naatram (smell)
5. Enjal (Deposits)

a) Niram (colour)

Nira thogai:

“பீதம் செம்மைபைங் கருமை வெண்மையென்

றோதங் கொழுமையை யொத்துகு நீரே

சித்த மருத்துவாங்கச் சுருக்கம் பக்கம் 510

The above poem reveals that urine colour as follows.

1. Yellow, 2. Red, 3. Green, 4. Black, 5. White.

கல்லடைப்பு நீரின் குணம் (Colour indicating urinary stone) :

“தீப்புலால் கழுநீர்ச் செயலென்ற குண்டிக்

காய்த்துர்ப் பலத்தால் கதித்த நீராமத்

துர்ப்பலக் கபமும் சோரியும் கொதிப்புறப்

பற்பக லாகப் பையைப் பதிந்தே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 520

The colour of the urine look like decomposed flesh cleaned water indicates the presence of kidney stones.

b) Edai (specific gravity)

“மிகத்தடிப் புமமிகத் தேறலும் இன்றெனில்

சுகத்தைத் தரும்மெய்ச் சுபாவநீர் நன்றே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 528

Urine which is not thick it is considered to be healthy one.

c) Nurai (Froth)

“பந்தமெய்ப் பசையிள கப்படும் பருவத்

தந்தர்ப் பூதமாய நிலமுத் திரத்தில்

சம்பந்தப் படும் ததி நுரைப் புனலே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 528

In normal condition, urine is frothy in nature. When these is reduced froth in the urine it indicates derangement of vali, Azhal, Iyyam.

d) Naatram (smell)

“காணிதில் சீழும் கலந்திழி மணமுறின்
கருப்பநா பிகளுளுங் காமநாளத்துளும்
விரணமுன் டின்றேன் எய்துமஸ் மரியல
திருத்தலே திண்ண மெனமனத் துன்னே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 519

The above poem states that foul colour with pyuria is observed in patient with urolithiasis is associated with secondary Urinary tract infection.

e) Enjal (Deposits)

“நார்த்தி நீர்பால் போல
நவையுற்றங் கிழியு மானால்
மாரற்ப முற்ற நீரி
லடிமண்டிக் கிடந்ந தானால்
பாரிந்த மெழுகு மாங்காய்
பற்றிய கல்லினாலே
சீருற்ற செய்கை யென்று
தெரிவுறசெப்ப லாமே

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 575

The colour of the urine excreted looks like curd water or milk and the presence of white colour and sand like deposits in urine indicated stones in the kidney.

2.1.11நெய்குறி (GENERAL EXAMINATION)

“அருந்துமா றிரதமும் அவிரோ தமதாய்
அ.கல் அலர்தல் அகாலவூண் தவிர்ந்தழற்
குற்றள வருந்தி உறங்கி வைகறை
ஆடிக் கலசத் தாவியெ காதுபெய்
தொருமுகூர்த் தக்கலைக் குட்படு நீரின்
நிறக்குறி நெய்குறி நிருமித்தல் கடனே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 509

Preparation of the patient:

On the day before the urine examination for Neikuri, the patient should be advised to take balanced diet and quantity of food must be proportionate to his appetite. In addition he/she should have a good sleep.

Method:

After waking up in the early morning, urine should be collected in a glass container and must be examined within 1 ½ hours. Then a drop of gingely oil should be added through the side of the container without any disturbance. The nature of neikuri should be noted under direct sunlight.

Observation :***Vatha Neer:***

“அரவென நீண்டின் அ.:தே வாதம்”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 532

In the drop of oil, lengthening like a snake it indicates vathaneer.

Pitha Neer:

“ஆழிபோற் பரவின் அ.:தேபித்தம்”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 533

In the drop of oil spreading like a ring, it indicates pitha neer.

Kabha Neer:

“முத்தொத்து நிற்கின் மொழி வதன் கபமே”

சித்த மருத்துவாங்கச் சுருக்கம், பக்கம் 534

In the drop of oil, remaining as that of pearl, it indicates kapha neer.

Thontha neer:

“அரவிலாலியும் ஆழியில் அரவும்

அரவின்முத்தும் ஆழியில் முத்தும்

தோற்றில் தொந்த தோடங்களாமே”

The thontha neer appears as a combination of the above pattern.

Mukkuutra neer:

The drop of oil immersing in to the urine, indicates Mukkuutraneer.

சாத்தியம், அசாத்தியம் (PROGNOSIS)

“சூட்டிட்ட சாத்தியத்தை சொல்லக் கேளாய்
சுளுக்காகும் வாரத்தின் கல்லடைப்பு
பூட்டிட்ட பித்தத்தின் கல்ல டைப்பு
புகழான சேட்டுமத்தின் கல்ல டைப்பு

மூட்டிட்ட இதுமூன்று மசாத்ய மாகி
முனையான மருந்துகளிற் செம்மை யாகும்
தோட்டிட்ட தொந்தமாங் கல்ல டைப்புத்
தொடுசுறவே கொல்லுமிது சூட்சந் தானே”

யூகி வைத்திய சிந்தாமணி 800

According to *YUGI VAIDHIYA CHINTHAMANI*-800 Vatha, Pitha, Kabha kalladaippu are curable and preventable, but Mukkuutra Kalladaippu is not curable.

According to *ROGA NIRNAYA SAARAM* under Rogam Nithanam, symptoms of kalladaippu noi like scrotal swelling and anuria are not curable.

2.1.12 LINE OF TREATMENT ADVOCATED AS PER THE SIDDHA PRINCIPLES:

In Urolithiasis, vatham and pitham are the two predominant factors which is responsible for the predisposition of stone formation, it is associated with heat and dryness. So the treatment should be planned towards the settlement of the affected humours as primary goal and secondary objective with medication towards the target action at specific sites and tertiary target to strengthen the system for the prevention of the disease.

As the above mentioned poem, purgation should be given to all patients as per their by condition.

kazhichal marunthu (purgatives) : Decoctions and mediated ghee with coolant properties are used to promote purgative to cleanse the colon bring about a balance of the impaired “TRIDHOSHAM”.

2.1.13 DIET:

Diet plays an important role in both prevention and protection of the body from stone diseases. Diet can contribute to the actiology, management or prevention of recurrence of kidney stone, because dietary ingredients and fluid intake influence the volume, PH and solute concentration of urine.

In urolithiasis, the diet should on with the target to promote the urination, washout the urinary bladder and to expel the small stones.

உணவு பழக்கவழக்கங்கள்:

உண்ணக்கூடியவை:

- குருவை, மணக்கத்தை அரிசி யாலாக்கிய சோறு உண்ண வேண்டும்.
- பார்லி அரிசிக்கஞ்சி, இளநீர் அருந்தவும்.
- முள்ளங்கி, வாழைத்தண்டு, அவரைக்காய், பூசணிக்காய், சுரைக்காய், கேரட், வெண்டைக்காய் சேர்க்க வேண்டும்.
- தர்பூசணி, பப்பாளி, கொய்யா, எலுமிச்சை சேர்க்கலாம்.
- பசலைக்கீரை, காசினிக்கீரை, கீரைத்தண்டு, வெள்ளரி விதை உண்ணவும்.

தவிர்க்க வேண்டியவை:

- தக்காளி, முட்டைகோஸ், காலிப்ளவர், உருளைகிழங்கு, காளான்.
- பால், காபி, டீ, மதுபானம், பதப்படுத்தப்பட்ட பானங்கள் அருந்தக்கூடாது.
- முட்டை, ஐஸ்கிரீம், சாக்லேட் தவிர்க்கவும்.

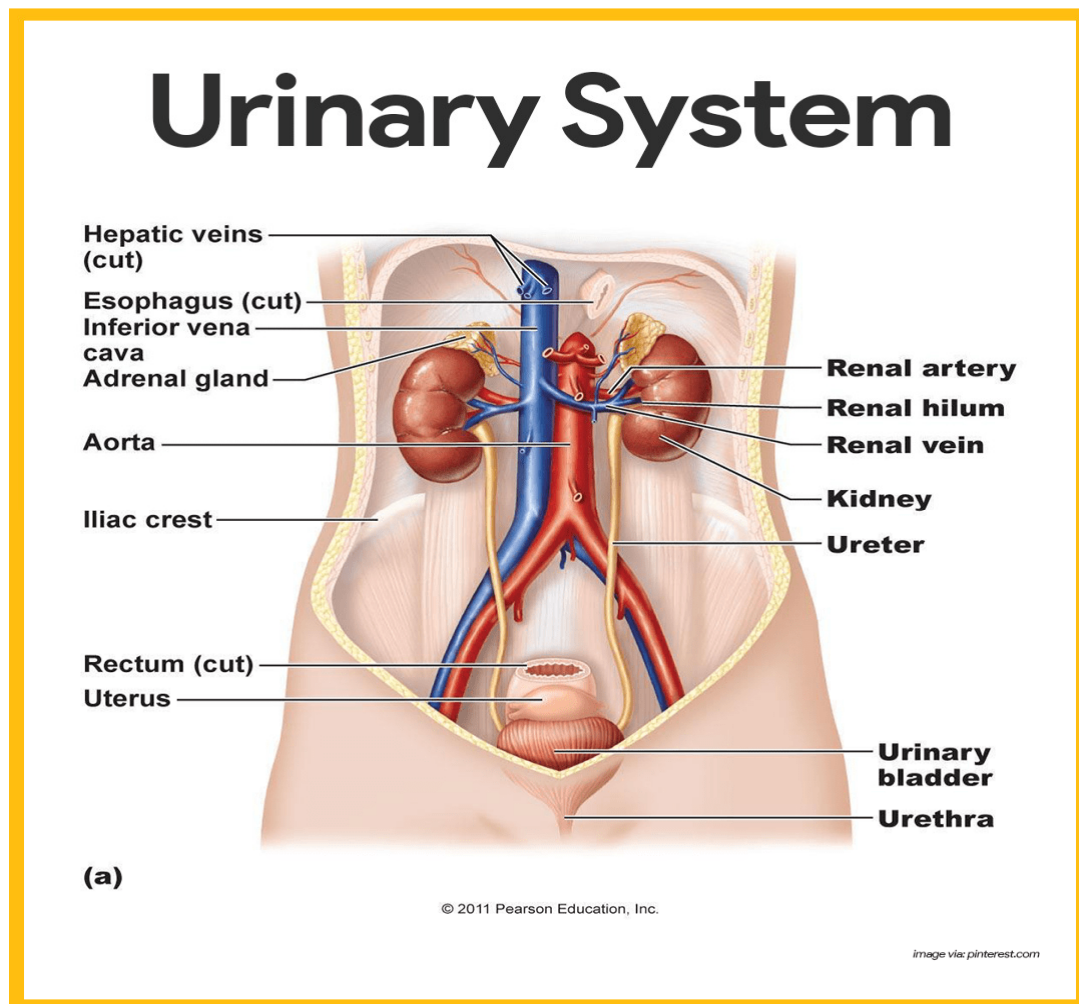
Advice :

1. Patient should drink large quantity of water (4 litre/day)
2. Patient should reduce salt intake
3. Regarding prevention “Anubhava Vaidhya Deva ragasiyam” states the one should not suppress the excretion of moothiram (Urine) and sukkilam (Seminal fluid) is most predisposing cause for Kalladaippu noi.

2.2 MODERN ASPECT

2.2.1 URINARY SYSTEM

The urinary system also known as the renal system consists of the kidneys, ureters, urinary bladder, and urethra. The purpose of the urinary system to eliminate waste from the body, regulate blood volume and blood pressure, control levels of electrolytes and metabolites and regulate blood PH. Following filtration of blood and further processing, wastes (in the form of urine) exit the kidney via the ureters, tubes made of smooth muscle fibres that propel urine towards the urinary bladder, where it is stored and subsequently expelled from the body by urination (voiding) through urethra.



2.2.2 UROLITHIASIS

Urolithiasis is the process of forming stones in the kidney, bladder, and or urethra. It is a solid concentration or crystal aggregation formed in the kidneys from dietary minerals in the urine. The common cause are blood in the urine and pain in the abdomen flank or groin region. The development of the stone is related to decreased urine volume or increased excretion of stone –forming components such as calcium, oxalate, urate, cystine, xanthine, and phosphate. It is estimated that approximately 2% of the population experiences renal stone disease at sometime in their life with male-female ratio of 2:1. The peak incidence is observed in 2nd and 3rd decades of life.

2.2.3 EPIDEMIOLOGY:

Hereditary:

Familial renal tubular acidosis are associated with nephrolithiasis in almost 70% of patients. Cystinuria, xanthinuria, are the disorders that causes renal stones. 15% of patients give a familial history of stone disease.

Age:

The peak incidence of urinary calculus in the age of 20-40 years.

Sex:

Males are mostly affected than females, because increased serum testosterone causes increased endogenous oxalate production in males.

Geographical influence:

The prevalence of urinary calculi is higher in those who live in mountains, desert, and tropical areas.

Climate and seasonal factors:

Incidence of urinary calculi and aggravation of symptoms are noted during summer months.

Water intake:

Urine dilution by increased water intake may increase ion activity coefficients and hence urinary crystallization, water diuresis reduces the average time of residence of free crystal particles in urine dilutes components of urine that may crystallize. Mineral contents of water may contribute to cause stone disease, (E.g Sodium Chlorides) zinc is an inhibitor of calcium crystallization.

Dehydration:

Not drinking enough water each day may increase risk of kidney stones people who live in warm climates and those who sweat a lot may be at higher risk than others.

Diet:

High oxalate, high calcium and high uric acid diets may promote stone disease. Vitamin-A, pyridoxine and magnesium are thought to inhibit stone disease.

PREDISPOSING FACTORS FOR URINARY STONES:**ENVIRONMENTAL AND DIETARY:**

- Low urine volumes: High body temperatures.

Low fluid intake.

- Diet: High protein intake.

High calcium intake.

- High sodium excretion.
- High oxalate excretion.
- Low citrate excretion.

ACQUIRED CAUSES:

Hypercalcaemia of any cause.

Renal tubular acidosis type-1

CONGENITAL AND INHERITED CAUSES:

Familial hypercalciuria.

Medullary sponge kidney.

Primary hyperoxaluria.

Cystinuria.

2.2.4 AETIOLOGY

1. *CALCIUM STONES:*

Aetiology of calcium stones is variable.

1. About 50% of patients with calcium stones have idiopathic hypercalciuria without hypercalcaemia.
2. Approximately 10% cases are associated with *hypercalcaemia* and *hypercalciuria*, most commonly due to hyperparathyroidism, or a defect in the bowel (i.e.,absorptive hypercalciuria), or in the kidney (i.e., renal hypercalciuria)
3. About 15% of the patients with calcium stones have *hyperuricosuria with* a normal blood uric acid level and without any abnormality of calcium metabolism.
4. In about 25% of patients with calcium stones, the cause is unknown as there is no abnormality in urinary excretion of calcium, uric acid or oxalate and is referred to as 'idiopathic calcium stone disease'.

2. *MIXED (STRUVITE) STONES:*

Struvite stones are formed as a result of infection of the urinary tract with urea-splitting organisms that produce urease such as by species of *Proteus*, and occasionally *Klebsiella*, *Pseudomonas* and *Enterobacter*. These are, therefore, also known as infection-induced stones. However, *E.coli* does not form urease.

3. *URIC ACID STONES:*

Uric acid stones are frequently formed in cases with hyperuricaemia and hyperuricosuria such as due to primary gout or secondary gout due to

myeloproliferative disorders (e.g. in leukaemias), especially those on chemotherapy, and administration of uricosuric drugs (e.g. salicylates, probenacid). Other factors contributing to their formation are acidic urine pH (below 6) and low urinary volume.

4. **CYSTINE STONES:**

Cystine stones are associated with cystinuria due to a genetically-determined defect in the transport of cystine and other amino acids across the cell membrane of renal tubules and the small intestinal mucosa.

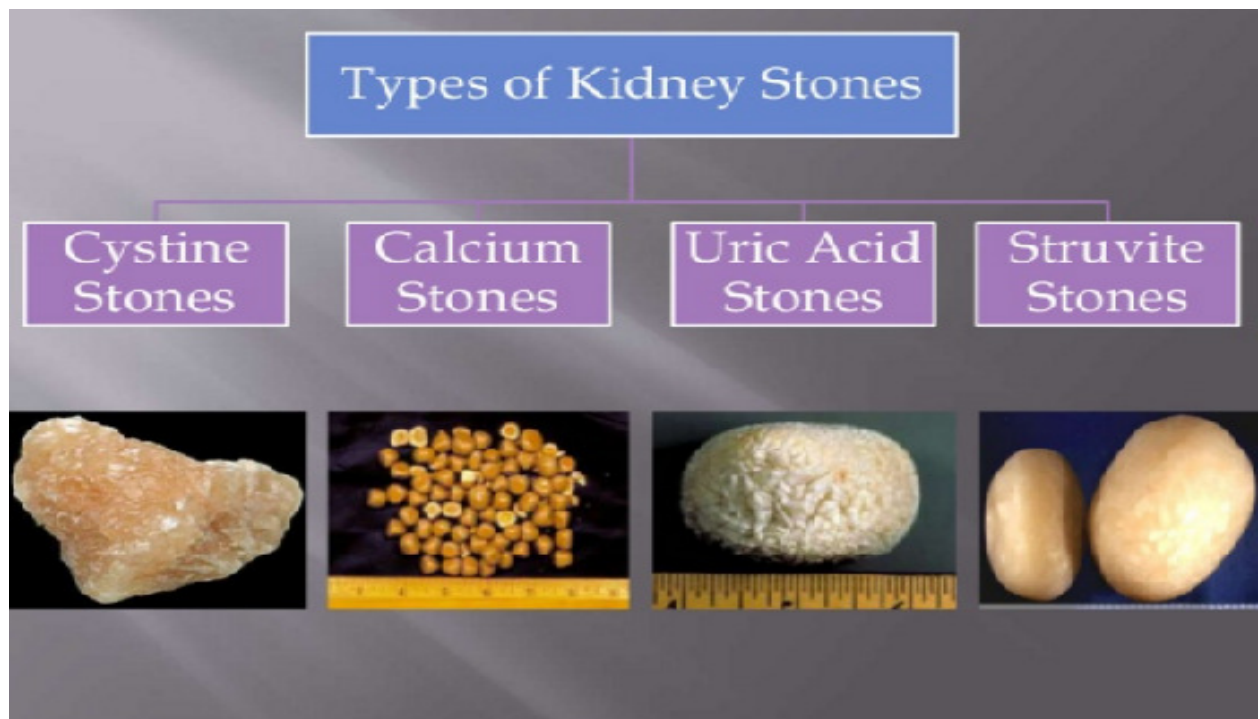
5. **OTHER CALCULI:**

Are caused due to inherited abnormality of enzyme metabolism.

2.2.5 TYPES OF URINARY STONES:

There are four types of urinary calculi, they are

1. Calcium type of stone-75%
2. Mixed (struvite) type of stone-15%
3. Uric acid type of stone-6%
4. Cystine type of stone-2%
5. other types-<2%



1. *CALCIUM STONES:*

Most kidney stones are made up of calcium compounds, especially calcium oxalate. Calcium stones are the most common comprising about 75% of all urinary calculi. They may be pure stones of calcium oxalate (50%) or calcium phosphate (5%) or a mixture of calcium oxalate and calcium phosphate (45%). Calcium stones are usually small (4-5mm), ovoid, hard, with granular rough surface. They are dark brown due to old blood pigment deposited in them and as a result of repeated trauma caused to the urinary tract by these sharp-edged stones. High levels of oxalate also increase in the risk for calcium stones.

2. *MIXED (STRUVITE) STONES:*

About 15% of urinary calculi are made of magnesium-ammonium-calcium phosphate, often called *struvite*, hence mixed stones are also called as struvite stones' or' triple phosphate stones.

Struvite stones are yellow-white or grey. They tend to be soft and friable and irregular in shape. '*Staghorn stone*' which is large, solitary stone that takes the shape of the renal pelvis where it is often formed is an example of struvite stone.

They can also be called infection stones if they occur with kidney or urinary tract infections. These types of kidney stones sometimes are also called staghorn calculi if they grow large enough.

3. *URIC ACID STONES:*

Approximately 6% of urinary calculi are made of uric acid. Uric acid stones are adiolucent unlike radio-opaque calcium stones. Uric acid stones are smooth, yellowish-brown, hard and often multiple. On cut section, they show laminated structure.

You are more likely to have uric acid stones if u have:

- Low urine output.
- A diet high in animal protein, such as red meat.
- An increase in how much alcohol you drink.
- Gout
- Inflammatory bowel disease.

4. CYSTINE STONES:

Cystine stones comprise less than 2% of urinary calculi. Cystine stones are small, rounded, smooth and often multiple. They are yellowish and waxy. They occur in both men and women who have the genetic disorder cystinuria.

5. OTHER CALCULI:

Less than 2% of urinary calculi consist of other rare types such as Xanthine stones.

This tabular column represented with prevalence of various stones and its colours

Kidney stone type	Population	Circumstances	Color	Sensitivity	Details
Calcium oxalate	80%	When urine is acidic (decreases PH)	Black/dark brown	Radio opaque	Some of the oxalate in urine is produced by the body. Calcium and oxalate in the diet play a part but are not the only factors that affect the formation of calcium
Calcium phosphate	5-10%	When urine is alkaline (high PH)	Dirty white	Radio opaque	Tends to grow in alkaline urine especially when proteus are present.
Uric acid	5-10%	When urine is persistently acidic.	Yellow reddish brown	Radiolucen t	Diets rich in animal proteins and purines: substances found naturally in all food but especially in organ meats, fish, and shellfish.
Struvite	10-15%	Infection in the Kidney	Dirty white	Radio opaque	Preventing struvite stones depends on staying infection-free. Diet has not been shown to affect struvite stone formation.
Cystine	1-2%	Rare genetic disorder	Pink/yellow	Radio opaque	Cysteine, an amino acid (one of the building blocks of protein) leaks through the kidneys and into the urine to form crystals.
Xanthine		Extremely	Brick red	Radio opaque	

2.2.6 PATHOGENESIS OF STONES

Urinary stones usually arise because of the breakdown of a delicate balance between solubility and precipitation of salts. The kidneys must conserve water, but they must excrete materials that have a low solubility. These two opposing requirements must be balanced during adaptation to diet, climate, and activity. The problem is mitigated to some extent by the fact that urine contains substances that inhibit crystallization. These protective mechanisms are less than perfect. When the urine becomes supersaturated with insoluble materials, because excretion rates are excessive and/or because water conservation is extreme, crystals form and may grow and aggregate to form a stone.

SUPERSATURATION:

A solution in equilibrium with crystals of calcium oxalate is said to be saturated with respect to calcium oxalate. If crystals are removed, and if either calcium or oxalate ions are added to the solution, the chemical activities increase, but no new crystals form. Such a solution is *metastably supersaturated*. If calcium oxalate crystals are now added, they will grow in size. Ultimately, as calcium or oxalate is added to the solution, supersaturation reaches a critical value at which a solid phase begins to develop spontaneously. This value is called the *upper limit of metastability*. Kidney stone growth requires a urine that, on average, is supersaturated. Excessive supersaturation is common in stone formation.

Calcium, oxalate, and phosphate form many soluble complexes among themselves and with other substances in urine, such as citrate. As a result, their free ion activities are below their chemical concentrations. Reduction in ligands such as citrate can increase ion activity and, therefore, supersaturation. Urine supersaturation can be increased by dehydration or by overexcretion of calcium, oxalate, phosphate, cystine, or uric acid. Urine pH is also important; phosphate and uric acid are acids that dissociate readily over the physiologic range of urine pH. Alkaline urine contains more dibasic phosphate, favoring deposits of brushite and apatite. Below a urine pH of 5.5, uric acid crystals (pK 5.47) predominate, whereas phosphate crystals are rare. The solubility of calcium oxalate is not influenced by changes in urine pH. Measurements of supersaturation in a 24-h urine sample probably underestimate the risk of precipitation. Transient, dehydration, variation of urine pH, and postprandial bursts of over excretion may cause values considerably above average.

CRYSTALLIZATION:

When urine supersaturation exceeds the upper limit of metastability, crystals begin to nucleate. Cell debris and other crystals present in the urinary tract can serve as templates for crystal formation, a process known as *heterogeneous nucleation*. Heterogeneous nucleation lowers the level of supersaturation required for crystal formation. Once formed, crystal nuclei will grow in size if urine is supersaturated with respect to that crystal phase. Multiple crystals can then aggregate to form a kidney stone.

In order for a kidney stone to form, crystals must be retained in the renal pelvis long enough to grow and aggregate to a clinically significant size. The mechanism of crystal retention has been a matter of much debate. Recent studies have shown that common calcium oxalate kidney stones form as overgrowths on apatite plaques in the renal papillae. These plaques, called Randall's plaques, provide an excellent surface for heterogeneous nucleation of calcium oxalate salts. The Randall's plaques begin in the deep medulla in the basement membrane of the thin limb of the loop of Henle and then spread through the interstitium to the basement membrane of the papillary urothelium. If the urothelium becomes damaged, the plaque is exposed to the urine, and calcium oxalate crystallization and stone formation begins.

INHIBITORS OF CRYSTAL FORMATION:

Urine contains potent inhibitors of nucleation, growth, and aggregation for calcium salts. Inorganic pyrophosphate is a potent inhibitor that appears to affect formation of calcium phosphate more than calcium oxalate crystals. Citrate inhibits crystal growth and nucleation, although most of the stone inhibitory activity of citrate is due to lowering urine supersaturation via complexation of calcium. Other urine components such as glycoproteins inhibit calcium oxalate crystallization.

1. CALCIUM STONES:

The mechanism of calcium stone formation is explained on the basis of imbalance between the degree of super saturation of the ions forming the stone and the concentration of inhibitors in the urine. Most likely site where the crystals of calcium oxalate and/or calcium phosphate are precipitated is the tubular lining or around some fragment of debris in the tubule acting as nidus of the stone. The stone grows, as more and more crystals are deposited around the nidus. A number of other predisposing factors contributing to formation of

calcium stones are alkaline urinary pH, decreased urinary volume and increased excretion of oxalate and uric acid.

2. MIXED (STRUVITE) STONES:

Struvite stones are formed as a result of infection of the urinary tract with urea-splitting organisms that produce urease.

3. URIC ACID STONES:

The solubility of uric acid at pH of 7 is 200 mg/dl while at pH of 5 is 15 mg/dl. Thus, as the urine becomes more acidic, the solubility of uric acid in urine decreases and precipitation of uric acid crystals increases favouring the formation of uric acid stones. Hyperuricosuria is the most important factor in the production of uric acid stones, while hyperuricaemia is found in about half the cases.

4. CYSTINE STONES:

The resultant excessive excretion of cystine which is least soluble of the naturally occurring amino acids leads to formation of crystals and eventually cystine calculi.

2.2.7 CLINICAL SYMPTOMS:

- Haematuria.
- Recurrent urinary tract infection.
- Painful urination.
- Sweating.

Renal colic pain typically comes in waves lasting for 20-30 minutes, beginning in the flank or lower back and often radiating to the groin region or genitalis.

➤ Kidney stone symptoms:

Stones in the kidney can become lodged at the junction of kidney and ureter (uretero pelvic junction), resulting in

- Severe colicky flank pain, pain can be localized at the costo vertebral angle.

- Haematuria may be present intermittently or persistently.

➤ ***Urethral stone symptoms:***

Stones that can pass into the ureter, it produce

- Acute, sharp spasm with intermittent colicky pain radiating to the lateral flank and around the umbilical region.
- Haematuria.
- As a stone passes through the distal ureter near the bladder.
- Nausea and vomiting.

➤ ***Bladder stone symptoms:***

Once a stone enters the bladder

- Dysuria and urgency and frequency of micturition may be the only symptoms experienced.
- Immediate relief of symptoms occurs once the stone passes out of bladder.

2.2.8 DIAGNOSIS:

The diagnosis of kidney stones on the basis of, information obtained from history and physical examination.

Other tests:

- ❖ Complete blood count (CBC), looking for neutrophilia, (increased neutrophil granulocyte count) suggestive of bacterial infection, as seen in setting of struvite stones.
- ❖ Blood tests for calcium, phosphorus, uric acid, and electrolytes.
- ❖ Blood urea nitrogen (BUN) and creatinine to assess kidney functioning.
- ❖ Urine analysis- microscopic examination of the urine, which show
 - Red blood cells.
 - Epithelial cells.
 - Urinary casts and crystals.
 - Pus cells.
- ❖ Abdomen x-rays.

- ❖ Ultra sound examination of the kidney.
- ❖ Intra venous pyelogram.
- ❖ Retrograde pyelogram.
- ❖ MRI of the abdomen and kidneys.
- ❖ Abdomen CT scan.
- ❖ Stone analysis is done of collected stones can establish their composition, which in turn can help future preventive and therapeutic management.

2.2.9 DIFFERENTIAL DIAGNOSIS:

- Appendicitis.
- Cholecystitis and cholelithiasis.
- Ectopic pregnancy and pelvic inflammatory disease.
- Pancreatitis.
- Gastric and duodenal ulcers.
- Pyelonephritis.
- Diverticulitis.

2.2.10 COMPLICATIONS:

Occasionally, stones can injured the kidneys by causing infectio, resulting in

- Recurrent UTI.
- Pyelonephritis.
- Obstructive Uropathy.
- Hydronephrosis.
- Acute or Chronic Renal Failure.

2.2.11 MEDICATION:

✓ LITHOTRIPSY:

Extra corporeal shock wave lithotripsy uses sound waves to breakup large stones, so they can more easily pass down the ureters into your bladder. This procedure can be uncomfortable and may require light anaesthesia.

✓ URETEROSCOPY:

When a stone is stuck in the ureter or bladder, your doctor may use an instrument called a ureteroscope to remove it. A small wire with a camera attached is inserted into the urethra and passed into the bladder. A small cage is used to snag the stone and remove it. The stone will be sent to analysis.

2.2.12 DIET FOR URINARY STONES:

✓ *CALCIUM STONES:*

- A diet that increase blood and urine levels of calcium, such as caffeine and sodium.
- Coffee, chocolate, cool drinks, must be avoided.
- Vitamin B6 is to reduce the urinary calcium levels.
- Oxalate rich foods like spinach, beet, black tea, and nut are also avoided.
- Also avoid vitamin C rich foods, because it converts to oxalate, oxalate excreted in urine.

✓ *STRUVITE STONES:*

- They modify their diet to increase the acidity of urine to inhibit bacterial growth. Urine acidifiers include specific tablets, animal proteins, and citrus fruits.

✓ *URIC ACID STONES:*

- Avoid animal sources of protein.
- Even vegetable sources of protein like pulses and grains are also restricted.

✓ *CYSTINE STONES:*

- Avoid fish and grains containing protein.
- The food which help to raise the PH of the urine such as vegetable juices and fruits can be taken.

CHAPTER-III

MATERIALS AND METHODS

3.1 STUDY DESIGNS AND CONDUCT OF THE STUDY:

A Prospective open labeled randomized clinical trial on “KALLADAIPPU” was carried out in the Post Graduate Department Of Pothu Maruthuvam from the study period of AUGUST 2017-JUNE2018 at Government Siddha Medical College and Hospital, Palayamkottai-627002. Tirunelveli, Tamilnadu.

The study was approved by Institutional Ethics Committee (IEC) (IEC, GSMC/3-IEC/2016-I-7/20.07.2016)

The study was registered in Clinical Trials Registry-India (CTRI) and the reference number is 2017/08//009576- AUGUST 31

The study was approved by Institutional Animal Ethics Committee (IAEC), SASTRA University held on 09.09.2017. CPCSEA approval number : 483/SASTRA/IAEC/RPP.

3.2 SAMPLE DESIGN:

Totally 40 patients were selected in Kalladaippu Noi, among 40 (20-Outpatients and 20-Inpatients) of both sexes between age groups of 20-60 years, were recruited for study and treated with the trial drug till the end of the study period.

3.3 CRITERIA FOR THE SELECTION OF PATIENTS:

For the present study, patients were selected based on the following criteria

- ✓ Ultra sonogram report, indicating the presence of renal calculus.
- ✓ Urine analysis report, indicating the presence of crystals, albumin and RBCS deposition in the urine.

Clinical history of patients with the following symptoms

- ✓ Renal colicky pain, Burning micturition, Oliguria, Haematuria, Nausea and Vomiting.

3.4 COLLECTION AND MAINTENANCE OF PATIENT'S DATABASE:

A proforma was prepared to collect details about the patients personal and family history, present symptoms, history of recent and past illness, laboratory investigations (including urine and blood analysis). Ultra sonogram, method adopted for the purpose of treatment and management of the disease and follow-up procedures. The details collected were recorded in proforma for each individual patient and database was maintained for all the patients.

3.5 SELECTION OF TRIAL MEDICINE:

The trial medicine, SIRU NERUNJIL KUDINEER (Internal) is selected based on their medicinal values in treating KALLADAIPPU NOI, mentioned in the Siddha literature GUNAPAADAM MOOLIGAI Page.no. 597.

The ingredient was collected, purified properly and prepared according to the literature. The drug is given to the patients for the entire course of treatment. References are enclosed in ANNEXURE-I

3.5.1 Pre Clinical Analysis of Trial Medicine:

All the pre clinical studies of my trial drug had included Bio chemical analysis, Physio-chemical analysis, Acute toxicity studies and Pharmacological studies has done and cross checked before beginning the trial.

A) Biochemical Analysis of the trial medicine:

Biochemical analysis of the trial medicine was performed at the Biochemistry unit of Government Siddha Medical College and Hospital, Palayamkottai. Experiments were conducted by the unit by following the standard procedures to known the presence of minerals. The results of the Biochemical Analysis and Inferences are given in ANNEXURE-II

B) Physiochemical Analysis of the trial medicine:

It was performed at the Chennai testing laboratory private limited, Chennai. Experiments were conducted by the unit by following standard procedures to known the presence of minerals and microbiology. The results of the physiochemical analysis and results are given in ANNEXURE-III

C) Acute Toxicity studies of the trial medicine:

Acute toxicity study for my trial drug was already done by DR.SUDHAHAR M.D(S) studied in Govt. Siddha Medical College, Palayamkottai. at the academic year of OCTOBER 2013 - OCTOBER2016. The study proposal number is PCP/IAEC/013/2015. was done at Periyar College Of Pharmaceutical Sciences, Trichy.

D) Pharmacological Analysis of the trial medicine:

Pharmacological actions of the trial medicine were studied at SASTRA University, Thanjavur. Experiments were conducted with albino rats by following the standard procedures to determine the Pharmacological actions like Lithotriptic effect. The procedure, results and inferences are given in ANNEXURE-IV

E) Microbial studies of the trial medicine:

Microbial study for my trial drug was done at Malar Diagnostic Centre, Tirunelveli. The results of Microbial analysis and results are given in ANNEXURE-V

3.6 INVESTIGATIONS:

The patients were subjected to the following investigations to establish the diagnosis. The investigations were carried out regularly before and after the treatment.

- Routine laboratory investigations such as blood examination was tested biochemically to know the present functional status of the body and also urine tests were tested to know any depositions and other pathological constituents.
- All the patients were subjected to USG Abdomen before and after the treatment. The USG reports of few patients are enclosed in ANNEXURE-VI
- During the course of treatment the expulsion of stones were analysed in a well reputed medical laboratory to determine the type of stones. The stone analysis reports are given ANNEXURE-VI.

3.7 OUTCOME OF THE STUDY:

The outcome of the study was measured by complete reduction of clinical symptoms and clearance /reduction in the size of renal calculus by confirm USG-Abdomen, using the following Urolithiasis symptoms score. The score of each case at the time of enrolment and at the end of treatment were compared and on its basis the patient was informed that he/she was symptoms free and cured.

Urolithiasis Symptom Score:**(Circle relevant number on each line)**

1. Pain/colic	0- No pain	1- Mild pain	2 -Moderate pain	3- Severe pain
2. Haematuria	0 –No Haematuria	1- Microscopic	2- Persistent	3 -Gross
3. Dysuria	0 -No dysuria	1- Mild dysuria	2- Moderate dysuria	3- Severe
4. Stone		1- Single stone	2- Multiple stone	
5. Size of Stones	0- Gravel < 03mm	1-3 mm to < 4 mm	2-4 mm to < 5 mm	3-5 mm and above
6. Position of stone in Kidney	0- no stone in Kidney	1-Pelvic ureteric junction	2- Pelvis of kidney	3 Calyces of kidney
7. Position of stone in ureter	0- no stone in Ureter	1- Lower part of ureter	2- Middle of ureter	3- Upper part of Ureter
8. Position of stone in Bladder	0 -no stone in Bladder	1 -Base of bladder	2- Intramural ureter	

Total scoring – 22, 1-7 mild, 8-14 moderate, 15-22 severe.

Symptoms score – (Some of 8 circled numbers)

CHAPTER IV

OBSERVATION AND RESULTS

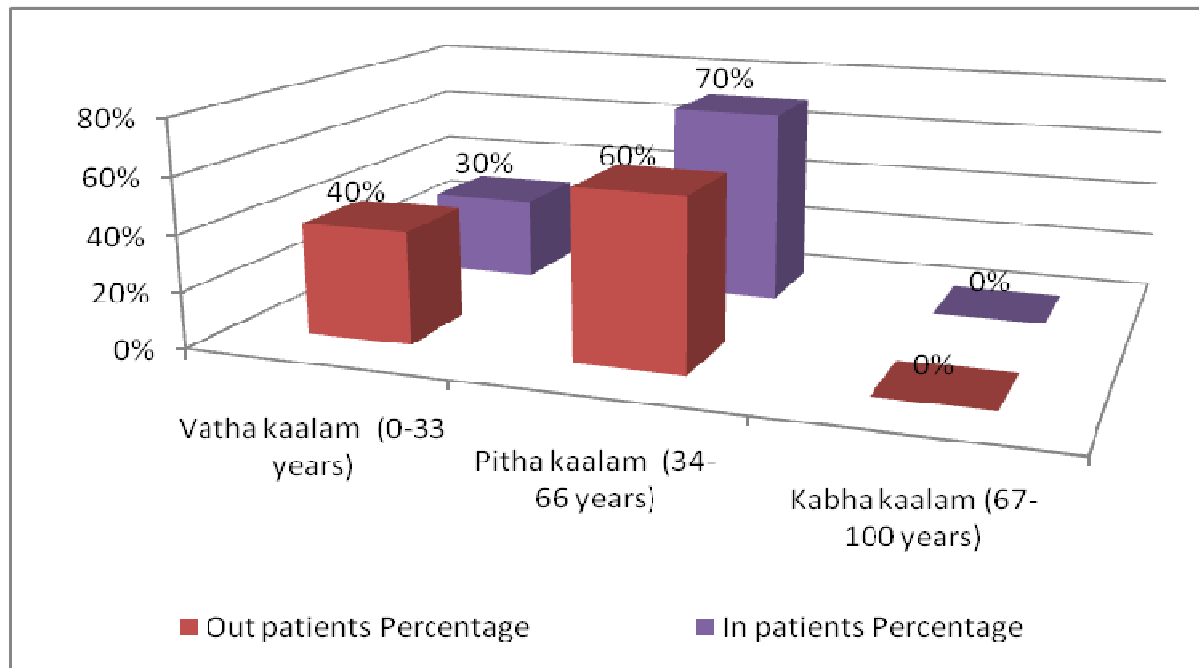
The results obtained from the presence study were recorded in the proforma with respect to the following parameters for each patient both out-patients and in-patients. They were analysed statistically in order to arrive at the percentage composition.

1. Age (Kalam) Distribution
2. Gender Distribution
3. Occupational Status
4. Dietary Habits
5. Marital Status
6. Personal Habits
7. Paruvakaalam (Season)
8. Thina (Land)
9. Thegathathuvam (Thegi)
10. Manothathuvam (Gunam)
11. Uyir Thathukal
 - a) Derangement of Vatham
 - b) Derangement of Pitham
 - c) Derangement of Kabam
12. Udal Thathukal
13. Kosangal
14. 14 Vegangal
15. Envagai Thervugal
16. Neerkuri
17. Neikuri
18. Duration of Illness
19. Number of Stones
20. Position of Stones
21. Size of Stones
22. Urolithiasis Symptoms Score
23. Grading outcomes of the study

Table 1 : AGE DISTRIBUTION

sl no	Age	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vatha kaalam (0-33 years)	8	40%	6	30%
2	Pitha kaalam (34-66 years)	12	60%	14	70%
3	Kabha kaalam (67-100 years)	0	0%	0	0%

Figure 1 : AGE DISTRIBUTION



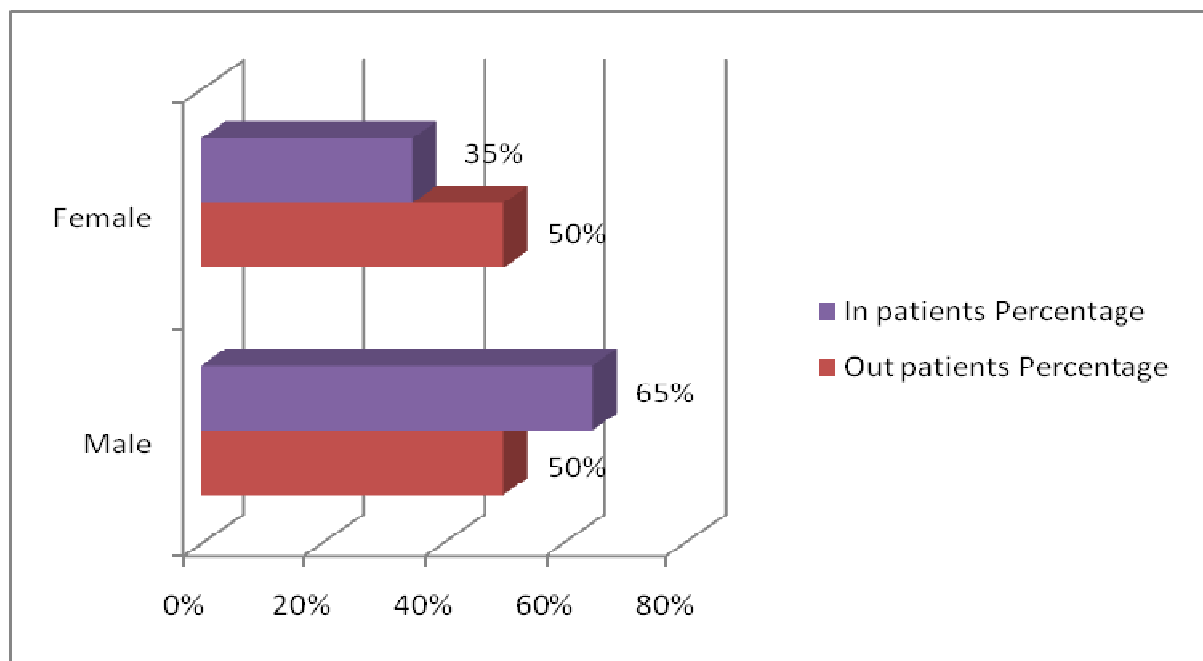
Inference:

The above table reveals that majority of both out patients 60% and in patients 70% comes under Pitha kaalam, 40% of outpatients and 30% of inpatients comes under Vatha kaalam.

Table 2 : GENDER DISTRIBUTION

sl no	Gender	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Male	10	50%	13	65%
2	Female	10	50%	7	35%

Figure 2 : GENDER DISTRIBUTION

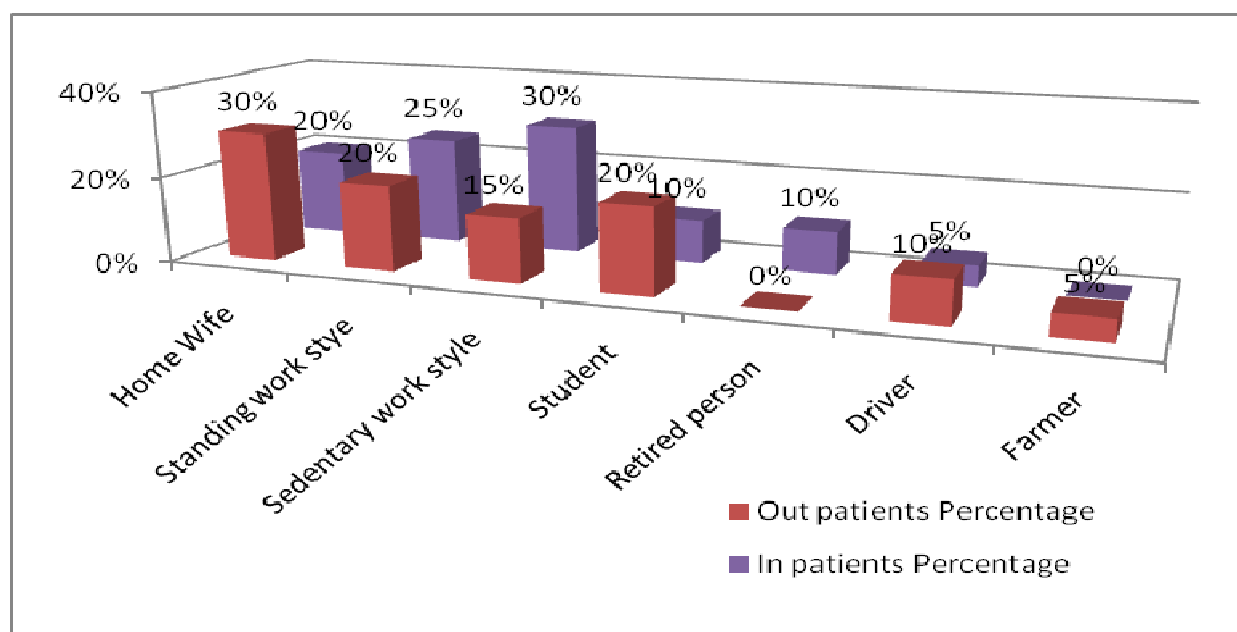


Inference:

From the above table, out patients (50%) of both Male and Female were equally affected. And inpatients 65% were Male and 35% were Female affected.

Table 3 : OCCUPATIONAL STATUS

sl no	Occupation	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	House Wife	6	30%	4	20%
2	Standing work style	4	20%	5	25%
3	Sedentary work style	3	15%	6	30%
4	Student	4	20%	2	10%
5	Retired person	0	0%	2	10%
6	Driver	2	10%	1	5%
7	Farmer	1	5%	0	0%

Figure 3 : OCCUPATIONAL STATUS

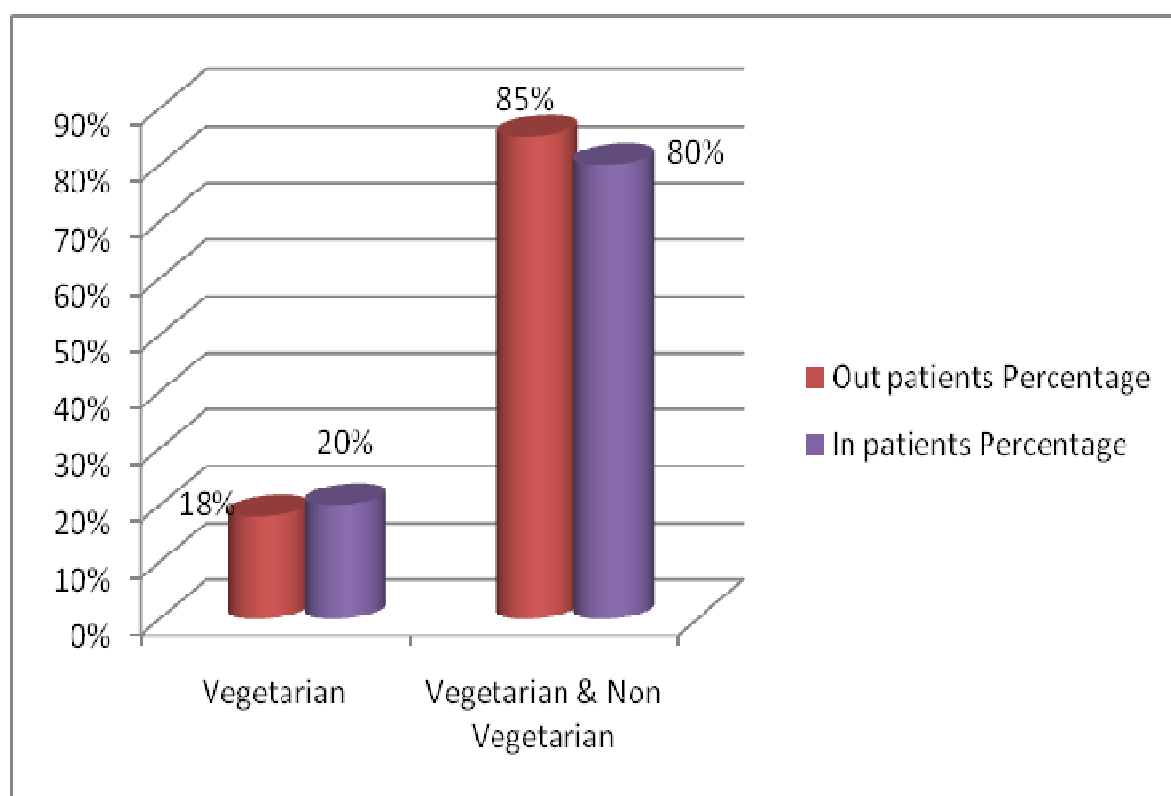
Inference:

Among out patients majority of them are House Wives 30%, compared to other Works. Among in patients majority of them are Sedentary Workers 30%, compared to other Works.

Table 4 : DIETARY HABITS

sl no	Diet	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vegetarian	3	18%	4	20%
2	Vegetarian & Non Vegetarian	17	85%	16	80%

Figure 4 : DIETARY HABITS



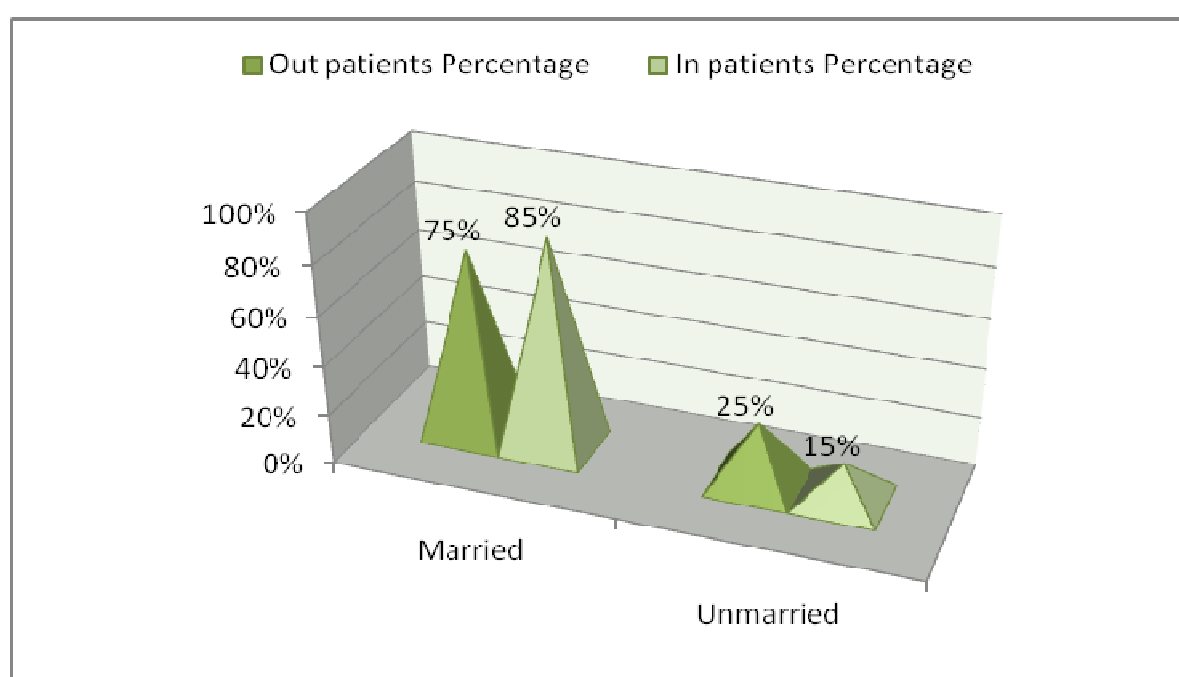
Inference:

This table reveals that majority of out patients 85% and in patients 80%, were both Vegetarian and Non- Vegetarian, compared to pure Vegetarian.

Table 5 : MARITAL STATUS

sl no	Marital	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Married	15	75%	17	85%
2	Unmarried	5	25%	3	15%

Figure 5 : MARITAL STATUS



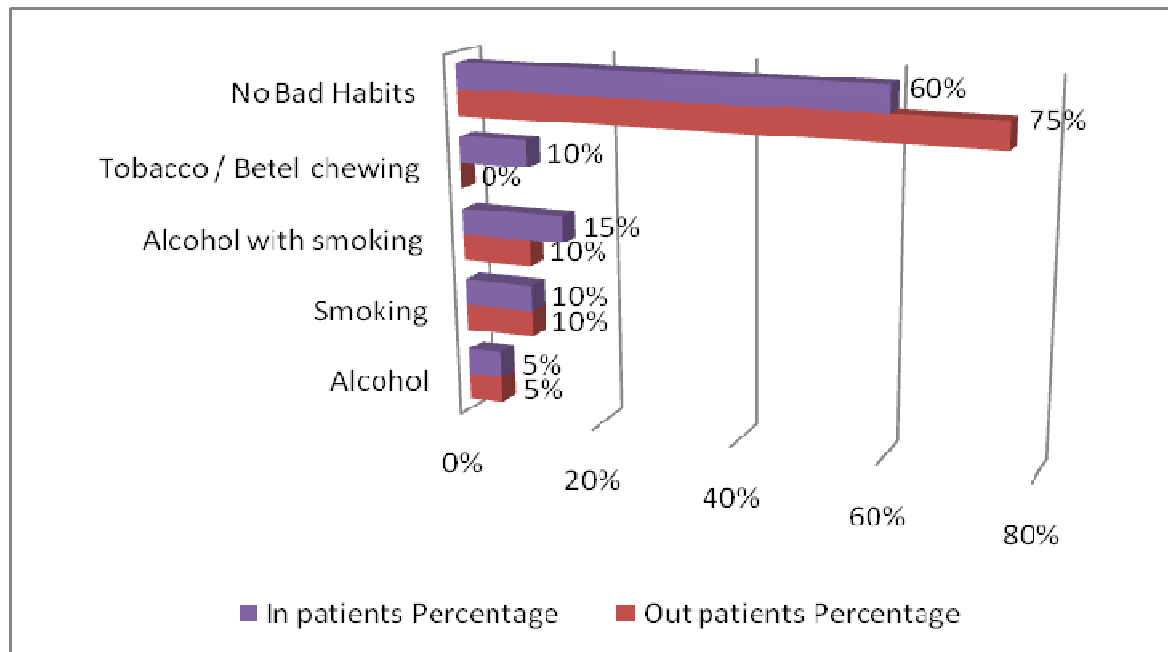
Inference:

This table reveals that majority of cases in out patients 75% and in patients 85% were Married, compared to Unmarried.

Table 6 : PERSONAL HABITS

sl no	Habits	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Alcohol	1	5%	1	5%
2	Smoking	2	10%	2	10%
3	Alcohol with smoking	2	10%	3	15%
4	Tobacco / Betel chewing	0	0%	2	10%
5	No Bad Habits	15	75%	12	60%

Figure 6 : PERSONAL HABITS



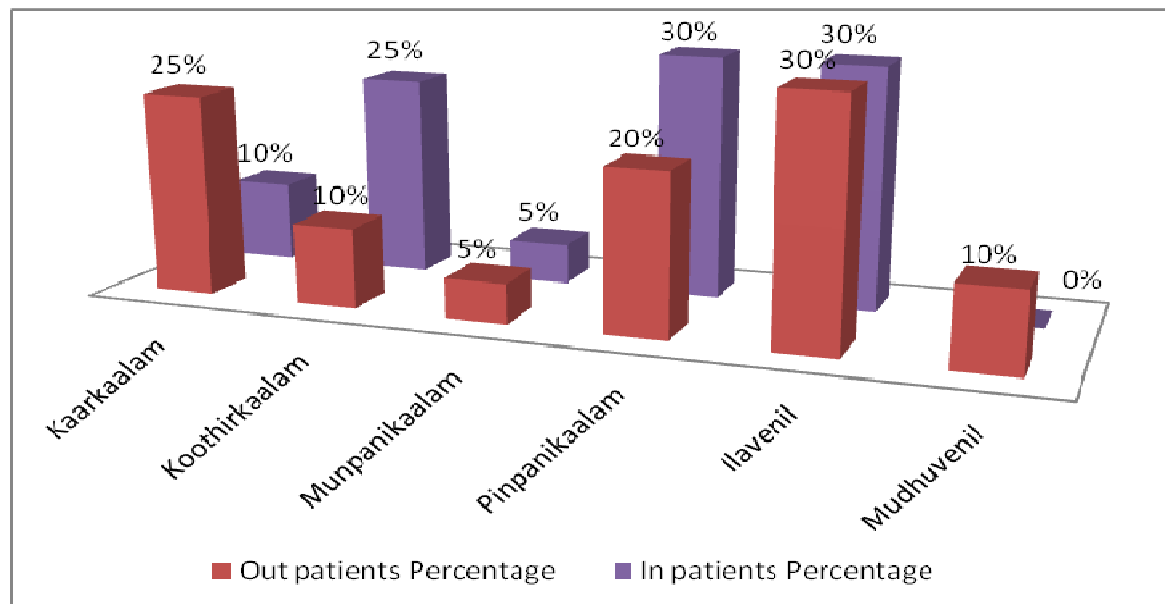
Inference:

This table reveals that majority of them out patients 75% and in patients 60% does not have Bad Habits, compared to other Bad Habits.

Table 7 : PARUVAKAALAM (SEASON)

sl no	Paruvakaalam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Kaarkaalam	5	25%	2	10%
2	Koothirkaalam	2	10%	5	25%
3	Munpanikaalam	1	5%	1	5%
4	Pinpanikaalam	4	20%	6	30%
5	Ilavenil	6	30%	6	30%
6	Mudhuvenil	2	10%	0	0%

Figure 7 : PARUVAKAALAM (SEASON)



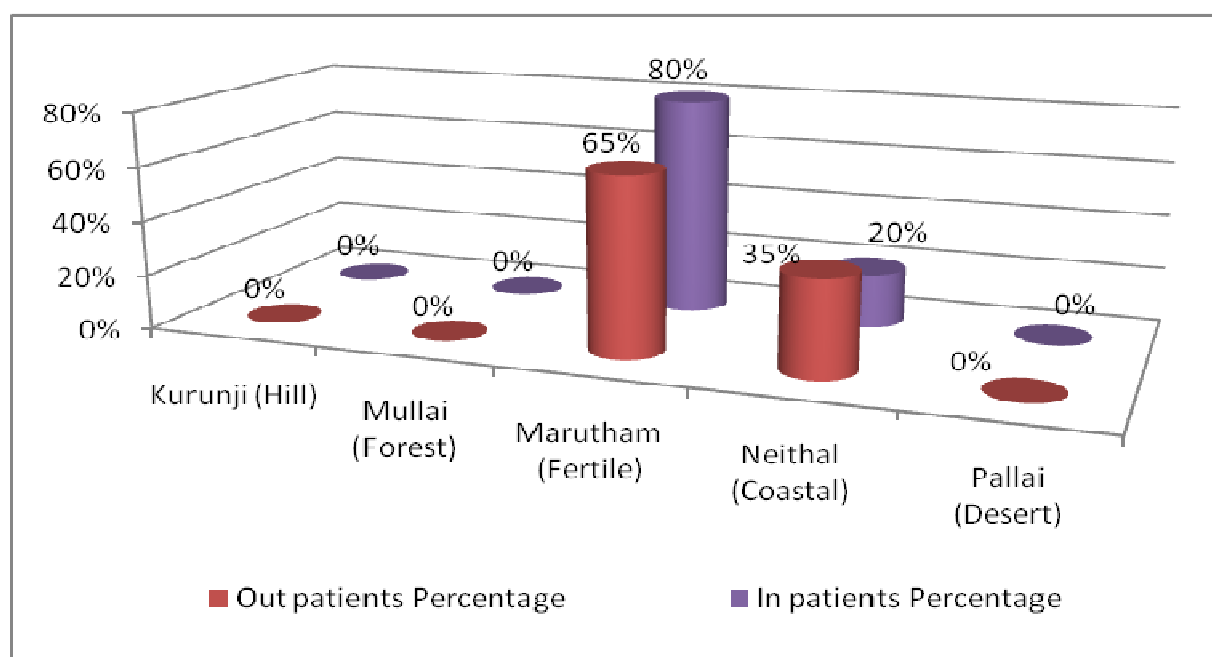
Inference:

Among out patients, majority of them were Ilavenil Kaalam 30%. And in patients, majority of them were Ilavenil Kaalam 30% and also Pinpani Kaalam 30%.

Table 8 : THINAI (LAND)

sl no	Thinai	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Kurunji (Hill)	0	0%	0	0%
2	Mullai (Forest)	0	0%	0	0%
3	Marutham (Fertile)	13	65%	16	80%
4	Neithal (Coastal)	7	35%	4	20%
5	Pallai (Desert)	0	0%	0	0%

Figure 8 : THINAI (LAND)



Inference:

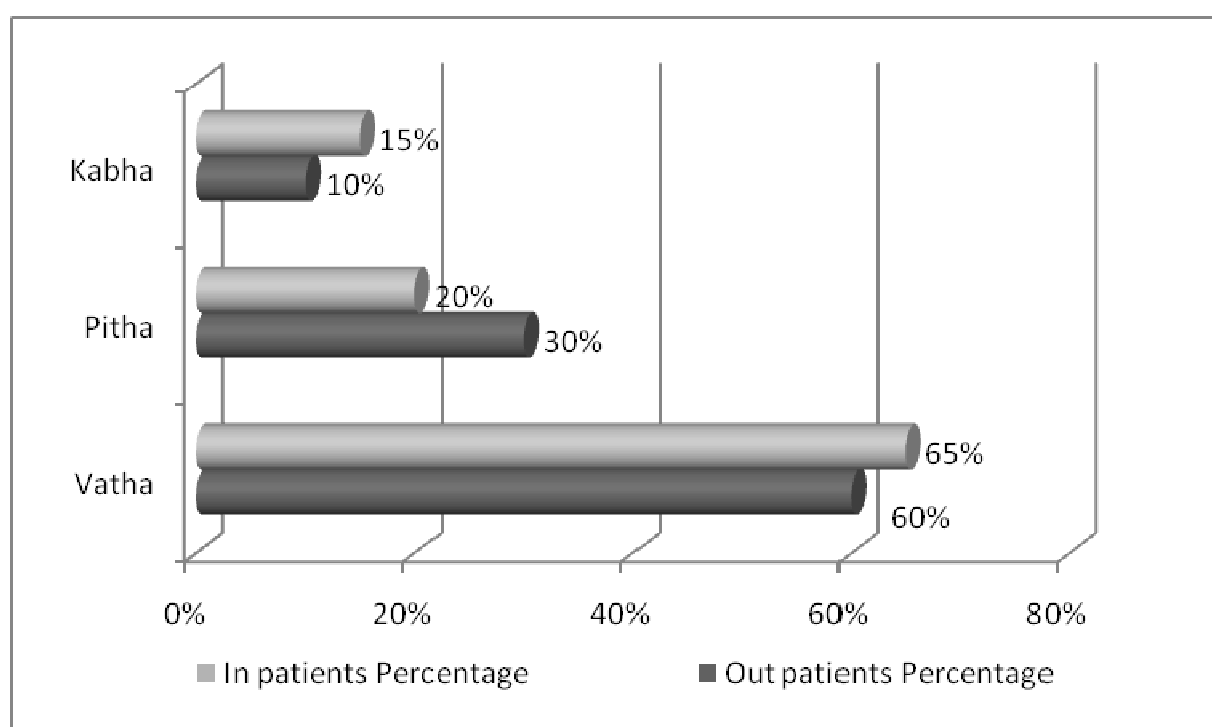
Among out patients, 65% were Marutham, 35% were Neithal.

Among in patients, 80% were Marutham, 20% were Neithal.

Table 9 : THEGA THATHUVAM

sl no	Thegi	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vatha	12	60%	13	65%
2	Pitha	6	30%	4	20%
3	Kabha	2	10%	3	15%

Figure 9 : THEGA THATHUVAM



Inference:

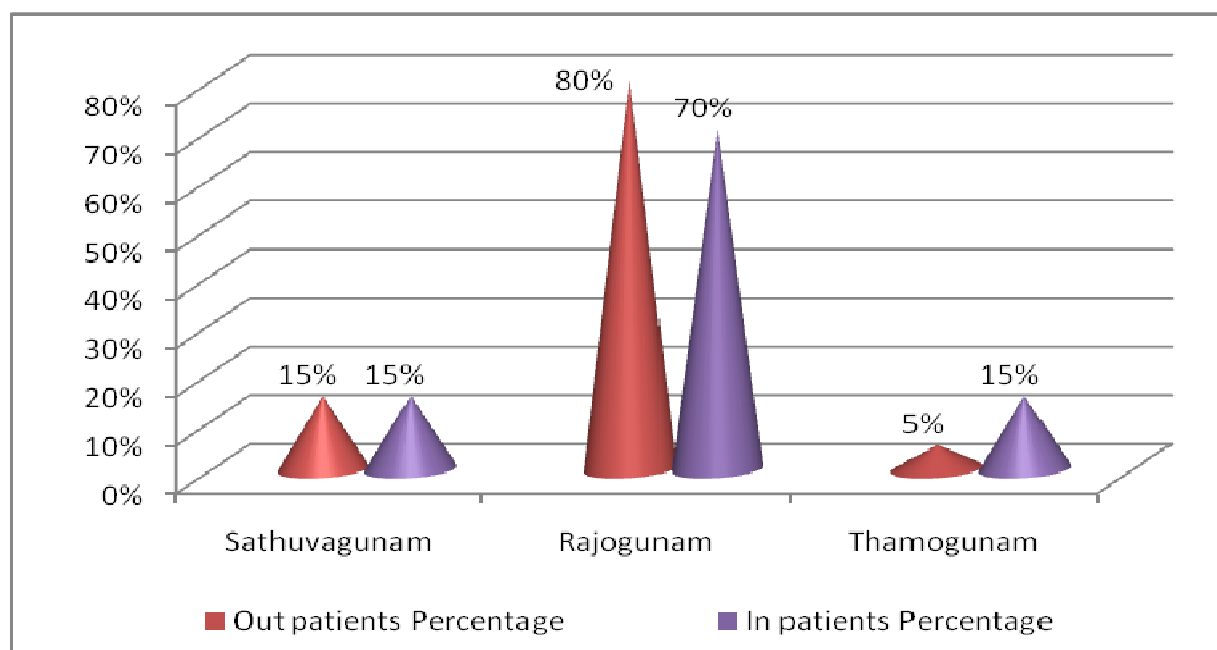
Among out patients, 60% were Vatha Thegi, 30% were Pitha Thegi, 10% were Kabha Thegi.

Among in patients, 65% were Vatha Thegi, 20% were Pitha Thegi, 15% were Kabha Thegi.

Table 10 : MANO THATHUVAM (GUNAM)

sl no	Gunam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Sathuvagunam	3	15%	3	15%
2	Rajogunam	16	80%	14	70%
3	Thamogunam	1	5%	3	15%

Figure 10 : MANO THATHUVAM (GUNAM)



Inference:

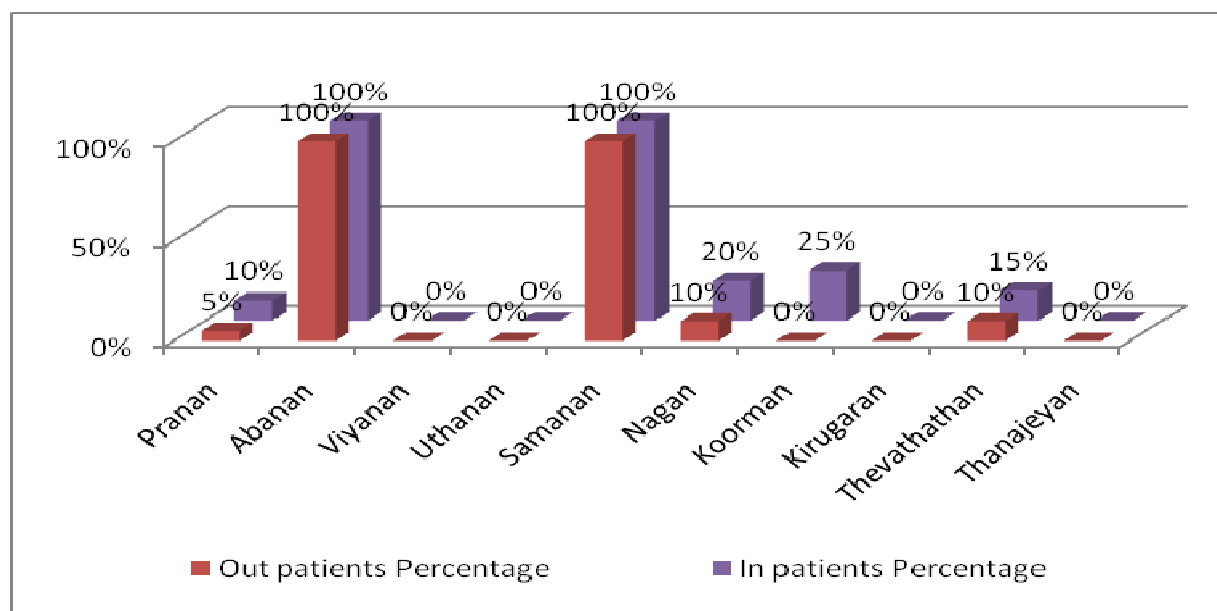
Among out patients, 80% were Rajogunam, 15% were Sathuvagunam, 5% were Thamogunam.

Among in patients, 70% were Rajogunam, 15% were Sathuvagunam, 15% were Thamogunam.

Table 11 : UYIR THATHUKAL
A) Derangement of Vatham

sl no	Vatham	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Pranan	1	5%	2	10%
2	Abanan	20	100%	20	100%
3	Viyanan	0	0%	0	0%
4	Uthanan	0	0%	0	0%
5	Samanan	20	100%	20	100%
6	Nagan	2	10%	4	20%
7	Koorman	0	0%	5	25%
8	Kirugaran	0	0%	0	0%
9	Thevathathan	2	10%	3	15%
10	Thanajeyan	0	0%	0	0%

Figure 11 A : Derangement of Vatham



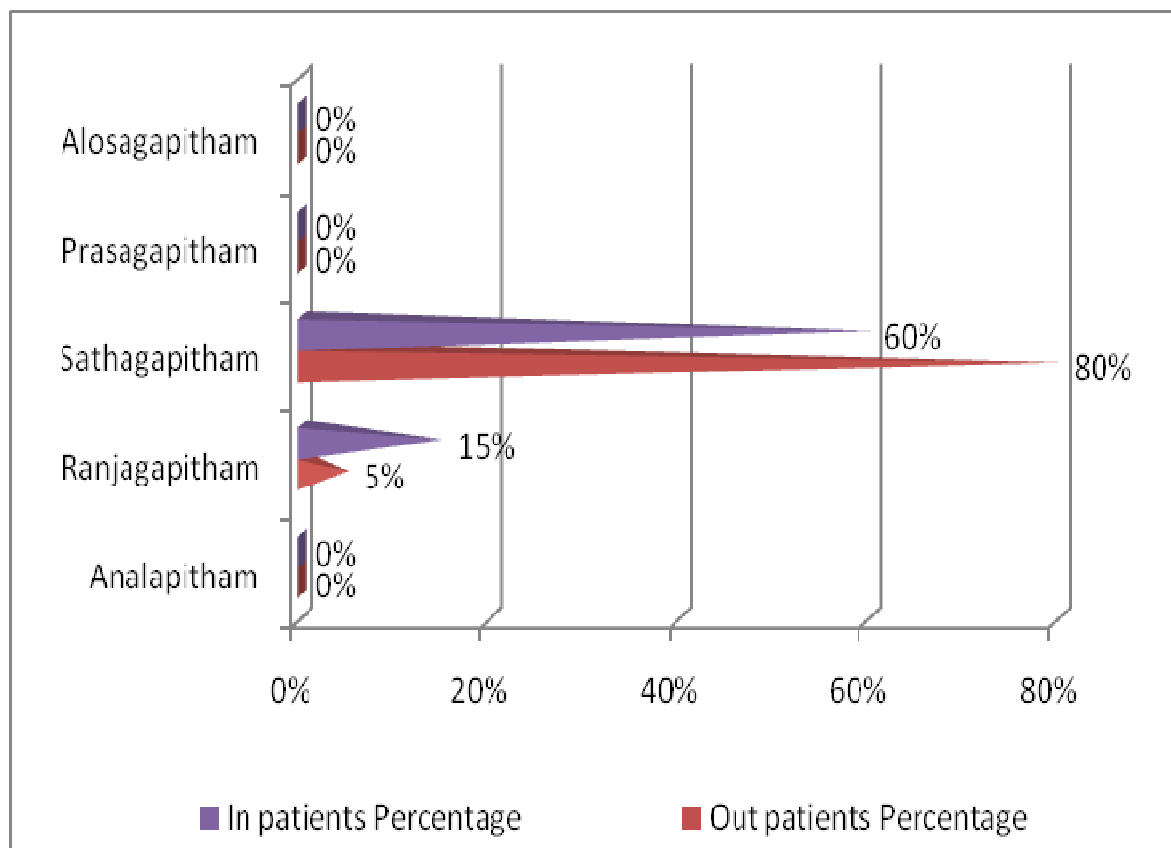
Inference:

This table reveals that all the out patients and in patients have Derangement in Abanan and Samanan Vayus 100% were affected, compared to other Vayus.

Table 11 : UYIR THATHUKAL
B) Derangement of Pitham

sl no	Pitham	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Analapitham	0	0%	0	0%
2	Ranjagapitham	1	5%	3	15%
3	Sathagapitham	16	80%	12	60%
4	Prasagapitham	0	0%	0	0%
5	Alosagapitham	0	0%	0	0%

Figure 11 B : Derangement of Pitham



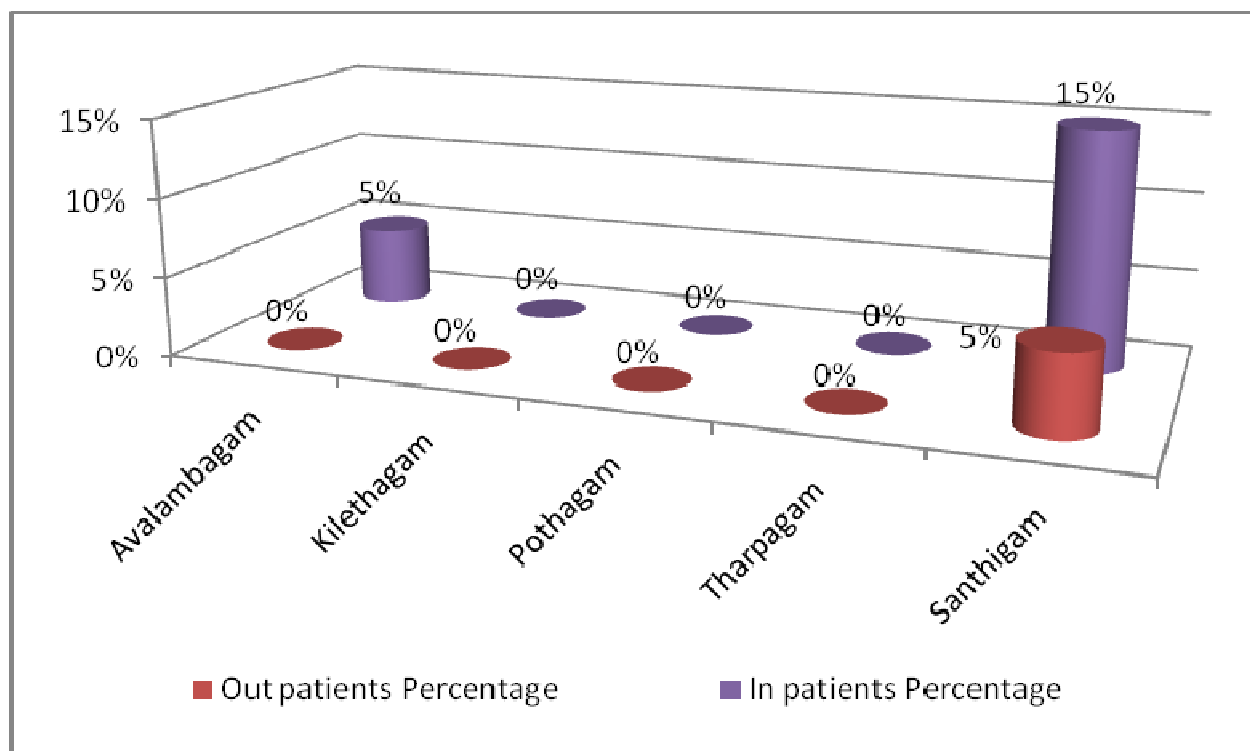
Inference:

This table reveals that majority of the out patients 80% and in patients 60% were affected in Sathagapitham. And few cases affected Ranjagapitham.

Table 11 : UYIR THATHUKAL
C) Derangement of Kabam

sl no	Kabam	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Avalambagam	0	0%	1	5%
2	Kilethagam	0	0%	0	0%
3	Pothagam	0	0%	0	0%
4	Tharpagam	0	0%	0	0%
5	Santhigam	1	5%	3	15%

Figure 11 C : Derangement of Kabam



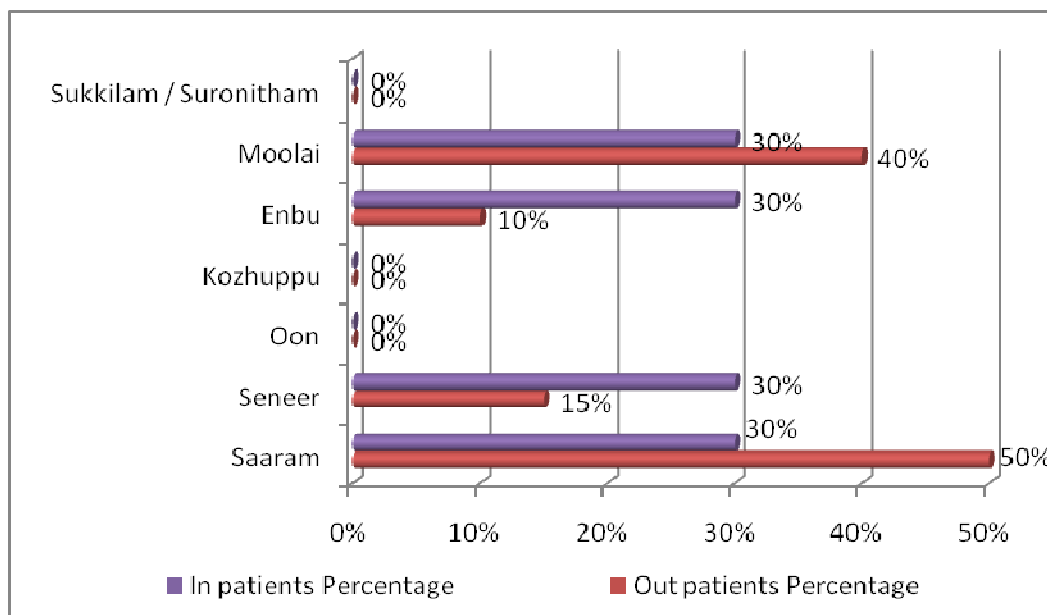
Inference:

This table reveals that majority of out patients 5% and in patients 15% was affected Santhigam. And few patients were affected Avalambagam.

Table 12 : UDAL THATHUKAL

sl no	Udal Thathukal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Saaram	10	50%	6	30%
2	Seneer	3	15%	6	30%
3	Oon	0	0%	0	0%
4	Kozhuppu	0	0%	0	0%
5	Enbu	2	10%	6	30%
6	Moolai	8	40%	6	30%
7	Sukkilam / Suronitham	0	0%	0	0%

Figure 12 : UDAL THATHUKAL



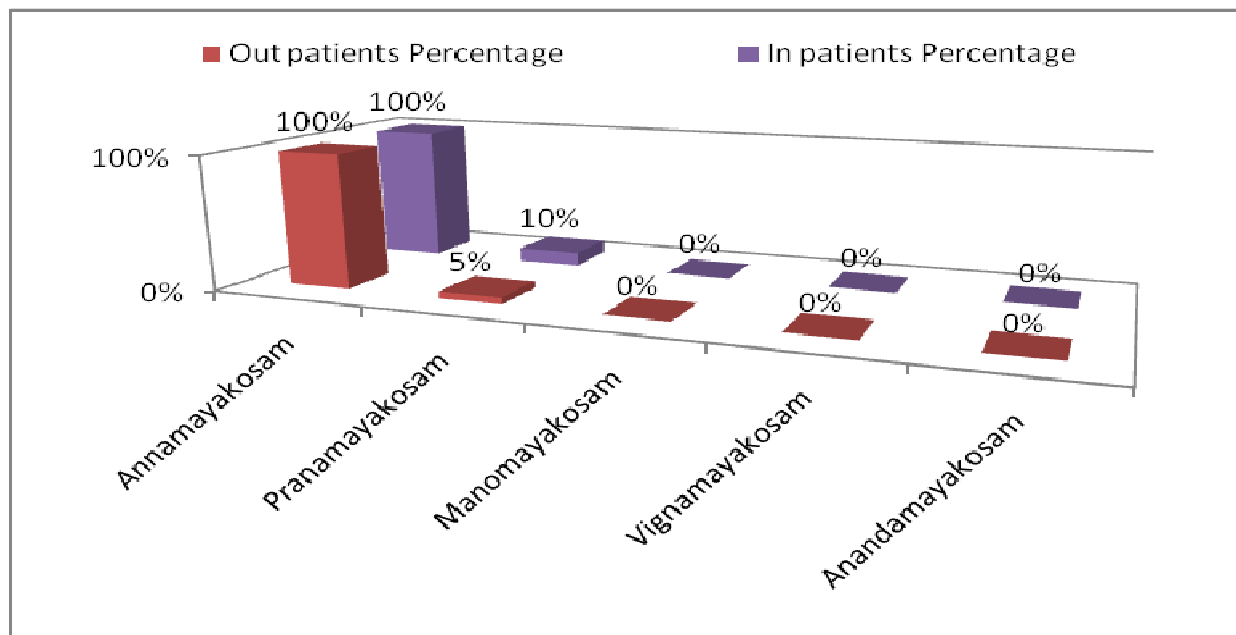
Inference:

This table reveals that majority of the out patients 50% and in patients 30% were affected by Saaram. And few cases were also affected by Moolai, Enbu, Seneer.

Table 13 : KOSANGAL

sl no	Kosangal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Annamayakosam	20	100%	20	100%
2	Pranamayakosam	1	5%	2	10%
3	Manomayakosam	0	0%	0	0%
4	Vignamayakosam	0	0%	0	0%
5	Anandamayakosam	0	0%	0	0%

Figure 13 : KOSANGAL



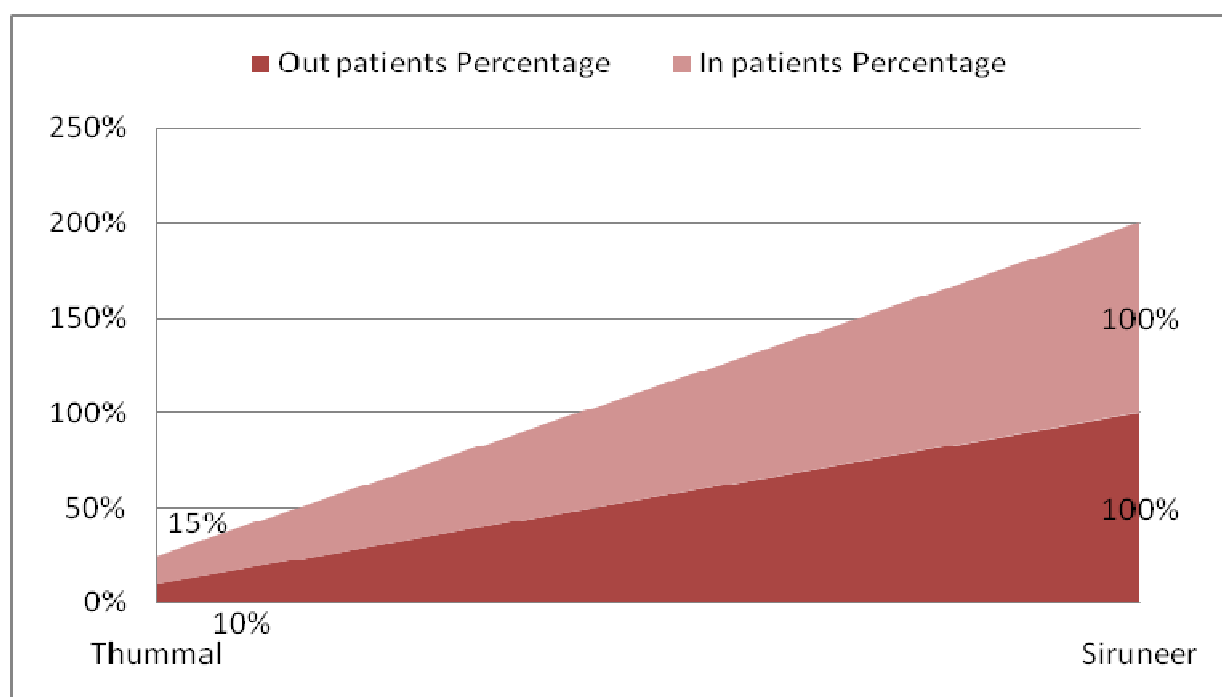
Inference:

This table reveals that majority of the out patients 100% and in patients 100% were affected by Annamayakosam. And few cases were affected by Pranamayakosam.

Table 14 : 14 VEGANGAL

sl no	Vegangal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Thummal	2	10%	3	15%
2	Siruneer	20	100%	20	100%

Figure 14 : 14 VEGANGAL



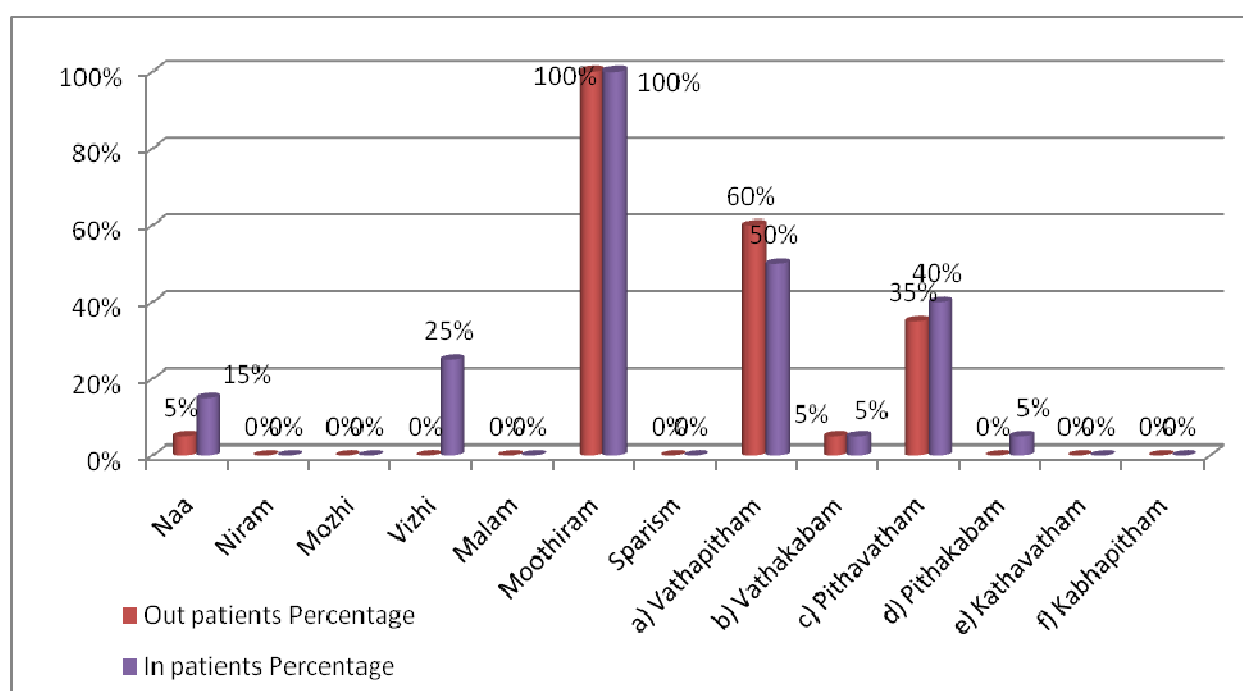
Inference:

This table reveals that majority of the out patients 100% and in patients 100% were affected by Siruneer. Few cases were affected by Thummal. And other vegangal were not affected.

Table 15 : ENVAGAI THERVUGAL

sl no	Envagai Thervugal	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Naa	1	5%	3	15%
2	Niram	0	0%	0	0%
3	Mozhi	0	0%	0	0%
4	Vizhi	0	0%	5	25%
5	Malam	0	0%	0	0%
6	Moothiram	20	100%	20	100%
7	Sparism	0	0%	0	0%
8	Naadi				
	a) Vathapitham	12	60%	10	50%
	b) Vathakabam	1	5%	1	5%
	c) Pithavatham	7	35%	8	40%
	d) Pithakabam	0	0%	1	5%
	e) Kathavatham	0	0%	0	0%
	f) Kabhapitham	0	0%	0	0%

Figure 15 : ENVAGAI THERVUGAL



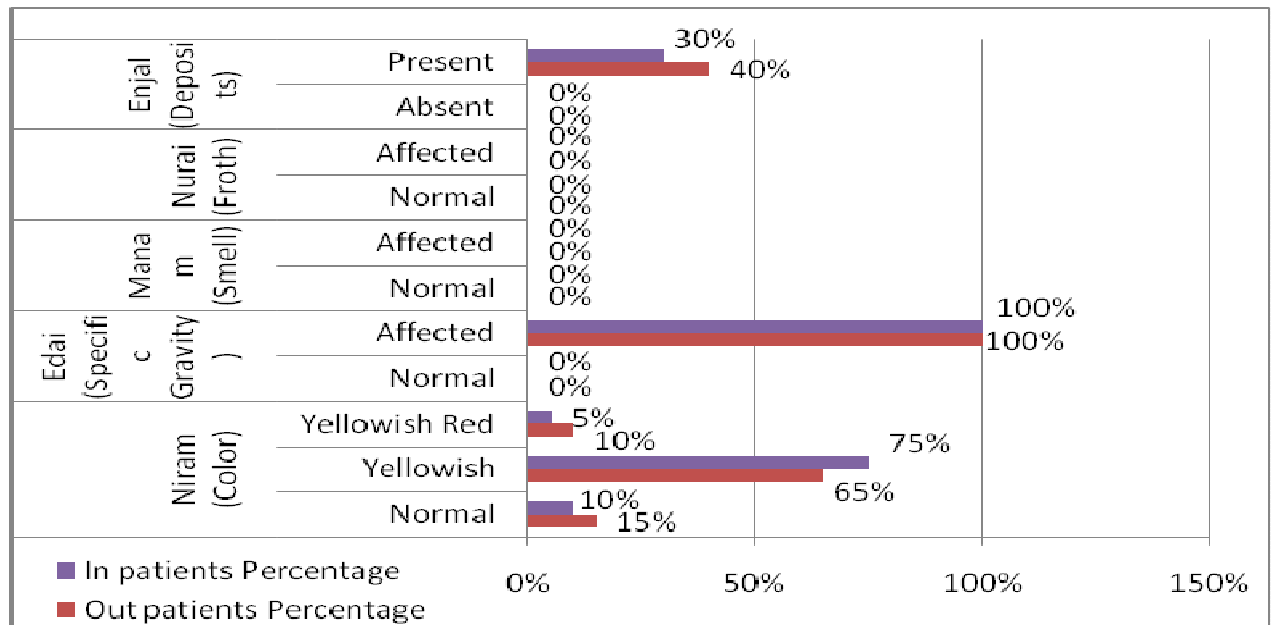
Inference:

This table understood that majority of the out patients 100% and in patients 100% that Moothiram was affected. And majority of cases Vathapitham naadi was mostly observed.

Table 16 : NEERKURI

sl no	Type of Test Result		Out patients		In patients	
			No. of Cases	Percentage	No. of Cases	Percentage
1	Niram (Color)	Normal	3	15%	2	10%
		Yellowish	13	65%	15	75%
		Yellowish Red	2	10%	1	5%
2	Edai (Specific Gravity)	Normal	0	0%	0	0%
		Affected	20	100%	20	100%
3	Manam (Smell)	Normal	0	0%	0	0%
		Affected	0	0%	0	0%
4	Nurai (Froth)	Normal	0	0%	0	0%
		Affected	0	0%	0	0%
5	Enjal (Deposits)	Absent	0	0%	0	0%
		Present	8	40%	6	30%

Figure 16 : NEERKURI



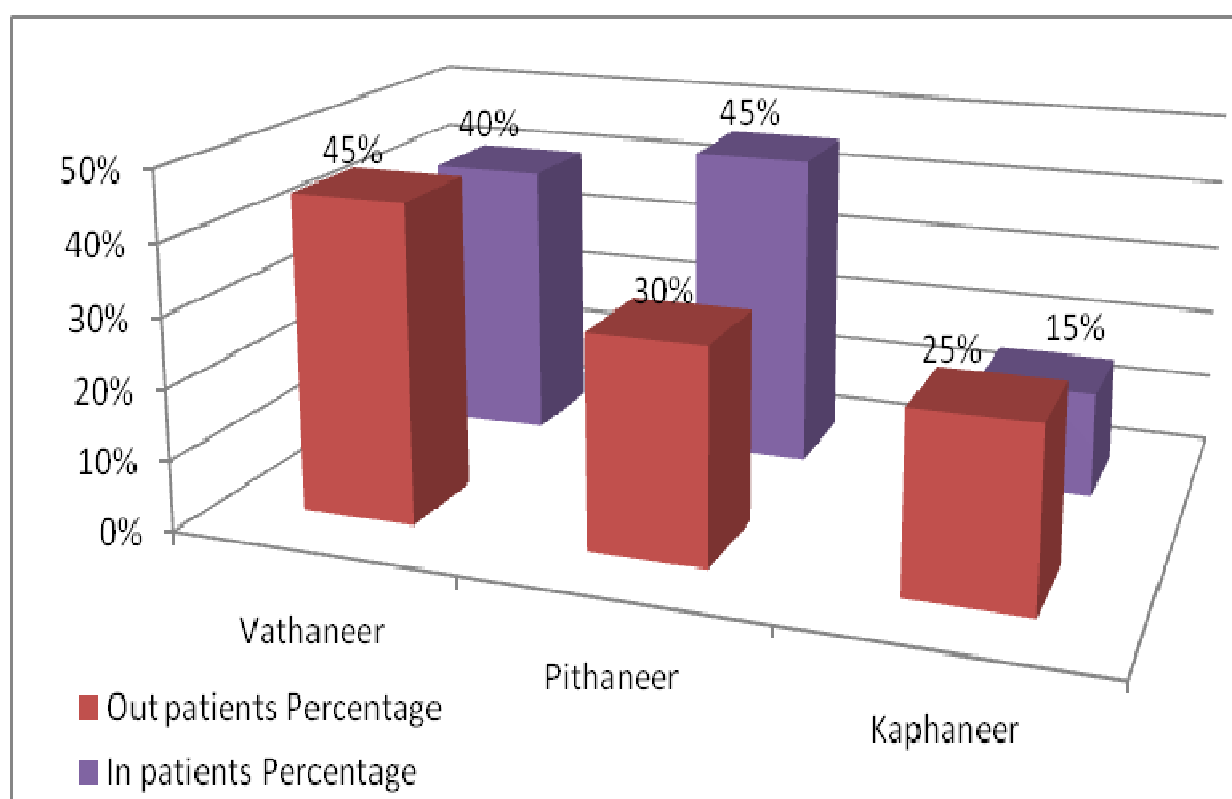
Inference:

Majority of patients have Yellowish Urine. All patients 100% were affected by Edai i.e Specific gravity. Enjal are also present in few patients.

Table 17 : NEIKURI

sl no	Neikuri	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Vathaneer	9	45%	8	40%
2	Pithaneer	6	30%	9	45%
3	Kaphaneer	5	25%	3	15%

Figure 17 : NEIKURI



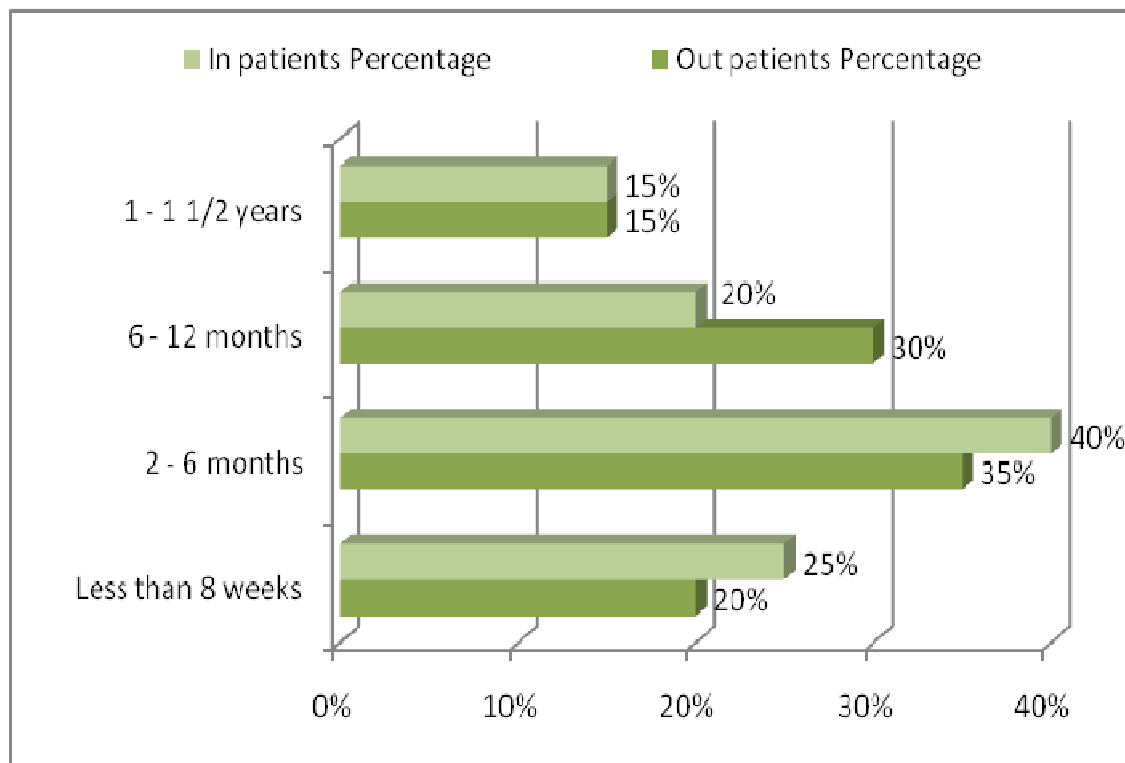
Inference:

Majority of the patients, have Vatha Neer (45% out patients and 40% in patients), and then Pitha Neer (30% out patients and 45% in patients), and also in few patients Kabha neer found.

Table 18 : DURATION OF ILLNESS

sl no	Duration	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Less than 8 weeks	4	20%	5	25%
2	2 - 6 months	7	35%	8	40%
3	6 - 12 months	6	30%	4	20%
4	1 - 1 1/2 years	3	15%	3	15%

Figure 18 : DURATION OF ILLNESS



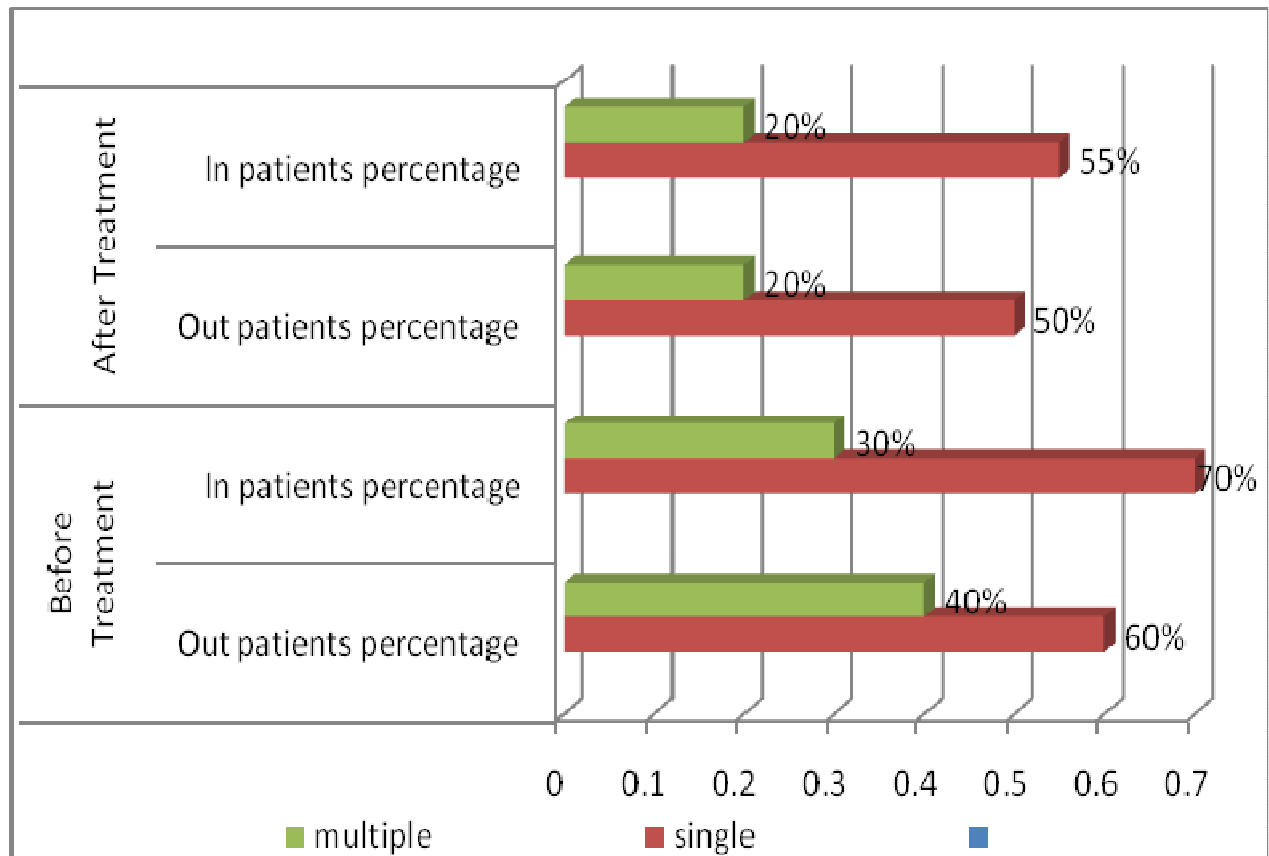
Inference:

During the time of period 2-6 months and 6-12 months have majority of out patients.
During the time of period 2-6 months and less than 8 weeks have majority of in patients.

Table 19 : NUMBER OF STONES

sl no	No. of Stones	Before Treatment				After Treatment			
		Out patients		In patients		Out patients		In patients	
		No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage	No of Cases	Percentage
1	Single	12	60%	14	70%	10	50%	11	55%
2	Multiple	8	40%	6	30%	4	20%	4	20%

Figure 19 : NUMBER OF STONES



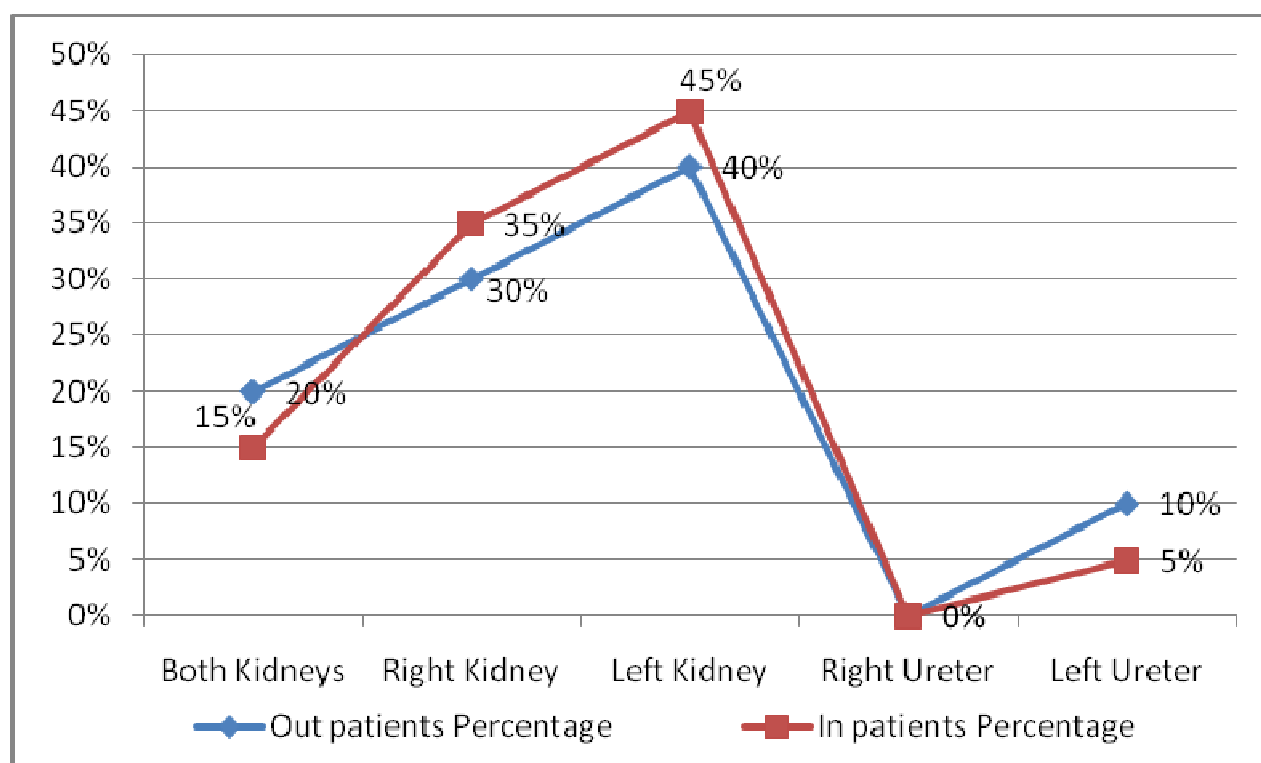
Inference:

This table reveals, before treatment majority of the (60% out and 70% in patients) has Single stone, and few cases has Multiple stones. But after treatment (50% out and 55% in patients) were Single stone, and few were Multiple stones.

Table 20 : POSITION OF STONES IN URINARY SYSTEM

sl no	Position of Stones	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Both Kidneys	4	20%	3	15%
2	Right Kidney	6	30%	7	35%
3	Left Kidney	8	40%	9	45%
4	Right Ureter	0	0%	0	0%
5	Left Ureter	2	10%	1	5%

Figure 20 : POSITION OF STONES IN URINARY SYSTEM



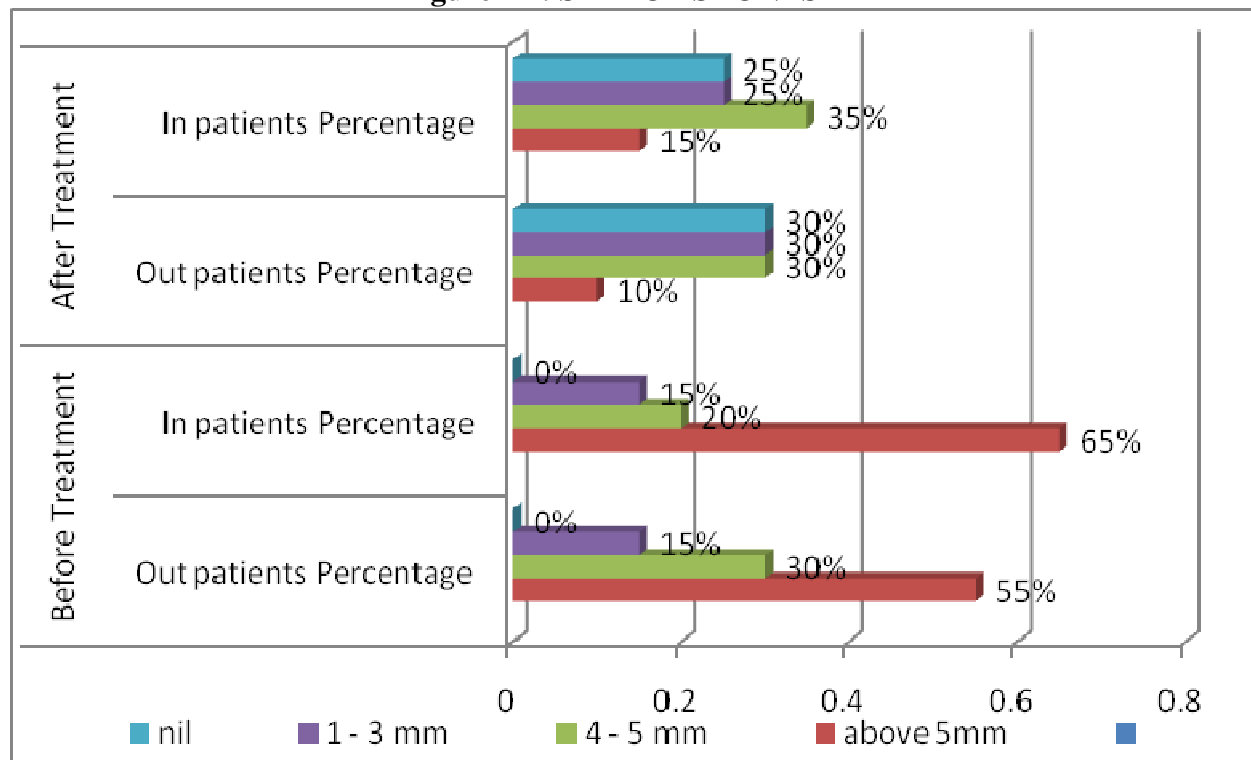
Inference:

Majority of cases of out patients 40% has calculi in Left Kidney . And also in patients 45% has calculi in Left Kidney.

Table 21 : SIZE OF STONES

sl no	Size of Stones	Before Treatment				After Treatment				P value
		Out patients		In patients		Out patients		In patients		
		No of Cases	Percent age	No of Cases	Percent age	No of Cases	Percent age	No of Cases	Percent age	
1	Above 5mm	11	55%	13	65%	2	10%	3	15%	<0.0001
2	4 - 5 mm	6	30%	4	20%	6	30%	7	35%	
3	1 – 3 mm	3	15%	3	15%	6	30%	5	25%	
4	nil	0	0%	0	0%	6	30%	5	25%	

Figure 21 : SIZE OF STONES



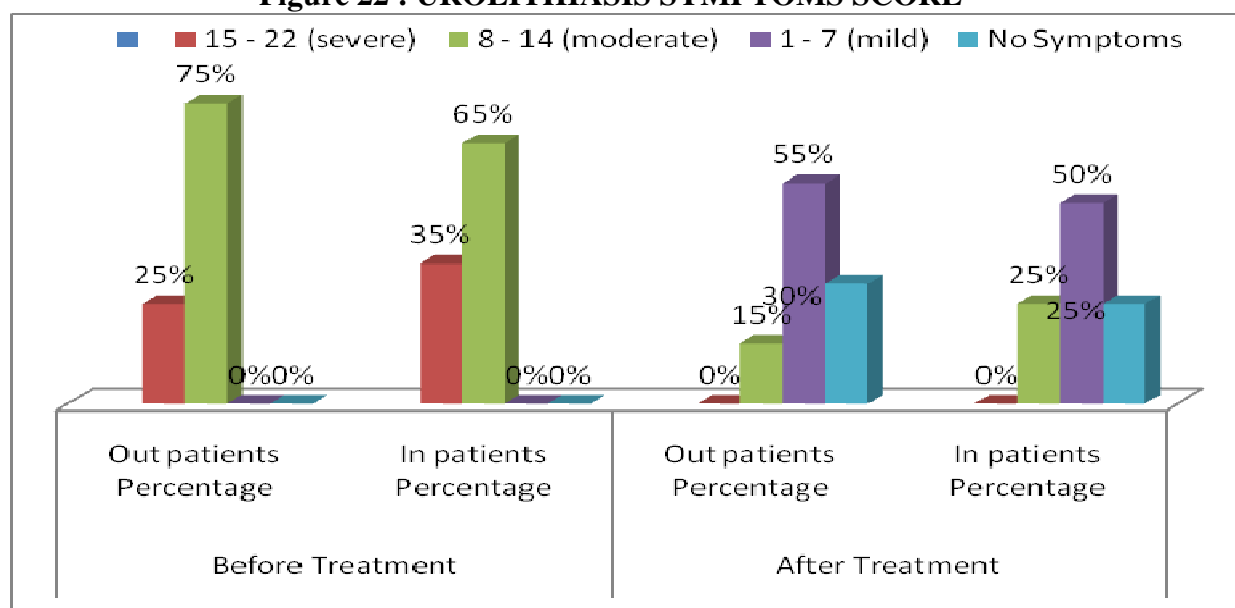
Inference:

Before treatment, the USG reports of majority of cases, stone size will be 5mm and above, and 4mm to <5mm in second major cases. After treatment majority of the cases, stone size will be upto <3mm. Thus the drug will be reduce the stone size. $P < 0.0001$ was considered statistically significant difference.

Table 22 : UROLITHIASIS SYMPTOMS SCORE

sl no	Types of score	Before				After				P value
		Out patients		In patients		Out patients		In patients		
		No of Cases	Percent age	No of Cases	Percent age	No of Cases	Percentage	No of Cases	Percentage	
1	15 - 22 (severe)	5	25%	7	35%	0	0%	0	0%	<0.0001
2	8 - 14 (moderate)	15	75%	13	65%	3	15%	5	25%	
3	1 - 7 (mild)	0	0%	0	0%	11	55%	10	50%	
4	No Symptoms	0	0%	0	0%	6	30%	5	25%	

Figure 22 : UROLITHIASIS SYMPTOMS SCORE



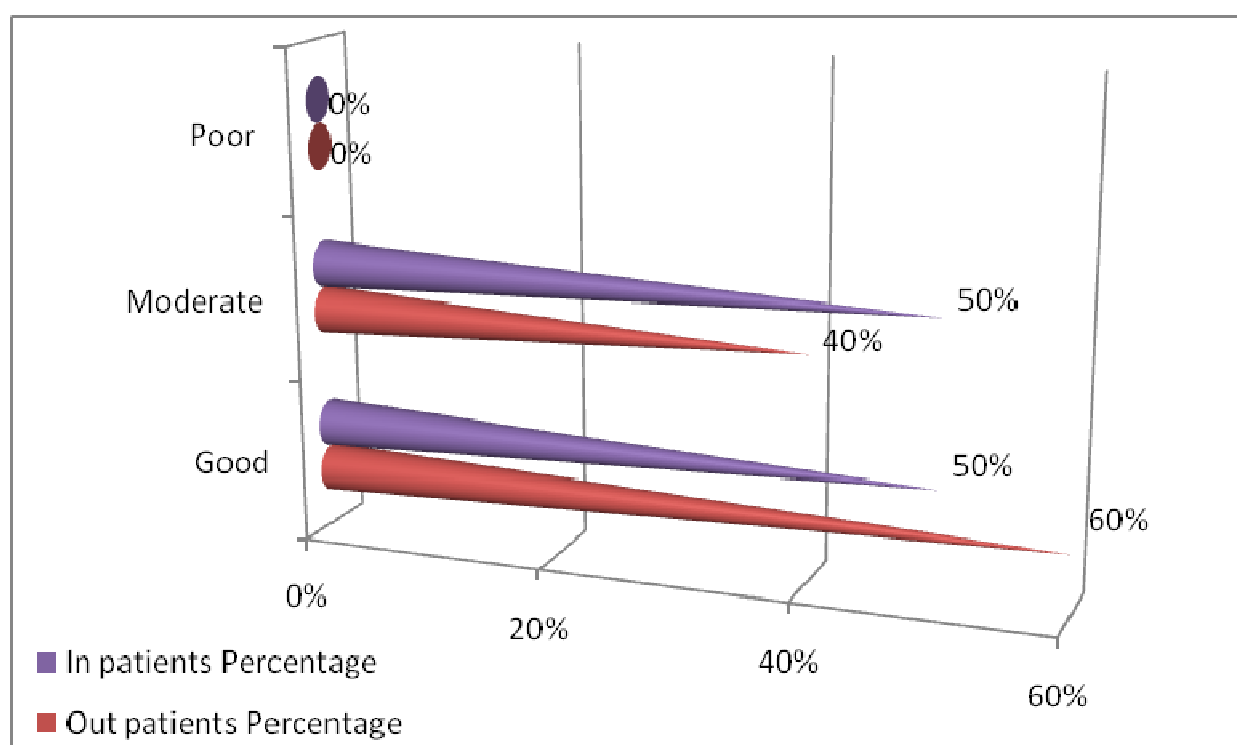
Inference:

The above table resembles that the score will be severe (out patients 25% and in patients 35%). And moderate in (75% of out patients and 65% of in patients),. Hence the score will be gradually decreased during treatment. And finally after the study (30% of out patients and 25% of in patients) have no symptoms. $P < 0.0001$ was considered statistically significant difference.

Table 23 : GRADING OUTCOMES OF THE STUDY

sl no	Types of Grading	Out patients		In patients	
		No. of Cases	Percentage	No. of Cases	Percentage
1	Good	12	60%	10	50%
2	Moderate	8	40%	10	50%
3	Poor	0	0%	0	0%

Figure 23 : GRADING OUTCOMES OF THE STUDY



Inference:

From the above table that majority of (out patients 60% and in patients 50%) have good response. Moderate response were observed in (40% of out patients and 50% of in patients). Thus the trial drug is very effective in curing kalladaippu noi.

CASE SHEET OF 20 OUT PATIENTS TREATED FOR KALLADAIPPU NOI

S.NO	OP.NO	NAME	AGE	SEX	STARTING OF TREATMENT	END OF TREATMENT.	NO OF DAYS TREATED	RESULT
1.	65904	Muthu Kumar	25	M	02/08/2017	03/09/2017	30 DAYS	FAIR
2.	68450	Ajanthan	37	M	10/08/2017	10/09/2017	30 DAYS	GOOD
3.	78294	Sadhish Kumar	34	M	11/09/2017	11/10/2017	30 DAYS	GOOD
4.	79107	Ganapathy	35	M	13/10/2017	13/10/2017	30 DAYS	GOOD
5.	79499	Pushpam	43	F	13/10/2017	13/10/2017	30 DAYS	GOOD
6.	83818	Velvizhi	42	F	27/09/2017	27/10/2017	30 DAYS	GOOD
7.	89095	Anbalagan	37	M	12/10/2017	12/11/2017	30 DAYS	GOOD
8.	98352	Muthu Kumar	29	M	08/11/2017	09/12/2017	30 DAYS	FAIR
9.	99207	Pushpalatha	40	F	10/11/2017	10/12/2017	30 DAYS	FAIR
10.	7286	Venkatachalam	45	M	28/01/2018	28/02/2018	30 DAYS	FAIR
11.	16863	Manikandan	23	M	02/03/2018	02/04/2018	30 DAYS	FAIR
12.	21195	Malar Vizhi	22	F	05/03/2018	05/04/2018	30 DAYS	GOOD
13.	33767	Shunmuga Sundarraaj	23	M	10/04/2018	10/05/2018	30 DAYS	GOOD
14.	33771	Karthicka	26	F	12/04/2018	12/05/2018	30 DAYS	GOOD
15.	34676	Sherma Pandian	34	M	23/04/2018	23/05/2018	30 DAYS	GOOD
16.	37388	Padma	48	F	23/04/2018	23/05/2018	30 DAYS	GOOD
17.	37393	Manimegalai	27	F	25/04/2018	25/05/2018	30 DAYS	GOOD
18.	38700	Vimala	46	F	28/04/2018	28/05/2018	30 DAYS	FAIR
19.	38615	Annamalai	33	F	30/04/2018	30/05/2018	30 DAYS	FAIR
20.	38691	Saraswathy	38	F	30/04/2018	30/05/2018	30 DAYS	FAIR

BLOOD INVESTIGATION

S. No.	OP No	Before Treatment							After Treatment						
		WBC Total cells / cub.mm	WBC-DC %			ESR		HB	WBC Total cells / cub.mm	WBC-DC %			ESR		HB
			P	L	E	½ hr	1 hr			P	L	E	½ hr	1 hr	
1.	65904	7300	66	30	4	-	21	12	6400	62	34	4	-	18	13
2.	68450	7000	60	36	4	-	12	13	6800	59	40	1	-	18	13
3.	78294	6500	62	35	3	-	15	13.7	7000	64	33	3	-	18	13.8
4.	79107	7200	54	45	1	-	15	12.4	8000	55	43	2	-	12	12.6
5.	79499	7600	64	32	4	-	20	9.8	7400	62	34	4	-	18	10
6.	83818	7500	64	27	4	-	16	10.5	7300	58	30	7	-	20	10
7.	89095	6800	64	32	4	-	24	12.6	7200	63	30	7	-	20	11.8
8.	98352	8000	60	36	4	-	15	14.3	7600	60	38	2	-	20	14
9.	99207	9800	64	33	1	-	15	11.5	8800	68	30	2	-	18	12
10.	7286	8000	58	41	1	-	25	13.5	7500	62	35	3	-	18	12.8
11.	16863	8800	63	34	3	-	18	11.5	8200	58	40	2	-	18	14
12.	21195	9300	60	35	5	-	12	10.5	8600	68	32	-	-	16	11
13.	33767	6900	76	20	4	-	15	14	8200	66	28	6	-	22	13.6
14.	33771	9800	64	33	3	-	15	11.5	8600	70	30	-	-	22	11
15.	34676	7000	58	38	4	-	15	12.5	7100	64	30	6	-	30	13
16.	37388	7500	68	29	3	-	17	13	7900	64	32	4	-	21	13.4
17.	37393	7500	67	29	4	-	10	10.5	8000	62	38	-	-	12	11.2
18.	38700	7300	60	37	3	-	10	11.6	7000	64	32	4	-	15	11
19.	38615	8000	60	36	4	-	12	14.4	7800	62	33	5	-	18	14
20.	38691	7800	58	31	1	-	16	11.6	7400	62	36	2	-	24	12

BIOCHEMICAL ANALYSIS

S.NO	OP.NO	Blood Sugar		Blood Urea		Total Cholesterol		Serum creatinine		Bilirubin	
		BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT
1.	65904	93	89	22	20	139	175	0.6	0.4	0.5	0.2
2.	68450	114	102	20	26	136	180	0.4	1.0	0.2	0.4
3.	78294	88	120	31	30	125	143	0.7	0.5	0.5	0.3
4.	79107	96	94	22	18	150	123	0.4	0.2	0.2	0.3
5.	79499	80	96	25	22	216	200	0.6	0.6	0.5	0.2
6.	83818	84	102	23	22	146	160	0.6	0.4	0.5	0.2
7.	89095	114	101	16	15	126	138	0.4	0.2	0.2	0.3
8.	98352	67	95	22	18	142	165	0.6	0.5	0.4	0.2
9.	99207	95	102	20	18	148	132	0.4	0.6	0.2	0.4
10.	7286	116	95	22	20	160	129	0.4	0.5	0.2	0.3
11.	16863	102	96	21	18	130	131	0.5	0.4	0.4	0.2
12.	21195	89	104	16	15	128	136	0.5	0.2	0.4	0.3
13.	33767	113	95	16	24	110	142	0.7	0.3	0.5	0.2
14.	33771	116	120	20	18	128	140	1.0	0.9	0.2	0.3
15.	34676	122	102	18	20	139	180	0.7	0.4	0.4	0.5
16.	37388	130	142	16	20	206	178	0.7	0.6	0.2	0.2
17.	37393	97	80	25	23	137	104	0.8	0.5	0.4	0.3
18.	38700	117	128	21	18	166	126	0.8	0.4	0.5	0.3
19.	38615	65	96	26	20	144	126	0.9	0.8	0.5	0.3
20.	38691	96	104	18	22	162	146	0.4	0.2	0.2	0.1

URINE ANALYSIS

S.NO	OP.NO	Before Treatment						After Treatment					
		Alb	Sugar	Pus cells	Epi. cells	RBC'S	casts/crystals	Alb	Sugar	Pus	Epi. cells	RBC'S	casts/crystals
1.	65904	Nil	Nil	1-2	NAD	0-3	NAD	Nil	Nil	0-1	NAD	NAD	NAD
2.	68450	Nil	Nil	2-5	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
3.	78294	Nil	Nil	5-7	1-2	NAD	NAD	Nil	Nil	1-2	0-1	NAD	NAD
4.	79107	Nil	Nil	1-2	2-3	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
5.	79499	Nil	Nil	2-5	1-2	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
6.	83818	Nil	Nil	5-7	Plenty	NAD	NAD	Nil	Nil	0-2	1-2	NAD	NAD
7.	89095	Nil	Nil	0-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
8.	98352	Nil	Nil	1-2	3-4	NAD	NAD	Nil	Nil	NAD	0-1	NAD	NAD
9.	99207	Nil	Nil	1-2	2-3	NAD	NAD	Nil	Nil	NAD	0-1	NAD	NAD
10.	7286	Nil	Nil	2-3	3-5	NAD	NAD	Nil	Nil	NAD	0-2	NAD	NAD
11.	16863	Nil	Nil	NAD	few	few	calcium oxalate crystals	Nil	Nil	NAD	0-2	0-1	NAD
12.	21195	Nil	Nil	few	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
13.	33767	Nil	Nil	NAD	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
14.	33771	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
15.	34676	Nil	Nil	5-8	3-5	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
16.	37388	Nil	Nil	few	1-2	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
17.	37393	Nil	Nil	3-5	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
18.	38700	Nil	Nil	1-2	2-3	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
19.	38615	Nil	Nil	1-2	NAD	NAD	Full of calcium oxalate	Nil	Nil	NAD	NAD	NAD	NAD
20.	38691	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD

CASE SHEET OF 20 IN PATIENTS TREATED FOR KALLADAIPPU NOI

S.NO	IP.NO	NAME	AGE	SEX	Starting of treatment	End of treatment	No.of days treated	Result
1.	2513	Karuppasamy	29	M	09/09/2017	10/10/2017	30 Days	Good
2.	2819	Paramasivan	45	M	21/10/2017	20/11/2017	29 Days	Fair
3.	3044	Murugan	40	M	14/11/2017	10/12/2017	26 Days	Good
4.	3047	Krishna	21	M	14/11/2017	14/12/2017	30 Days	Good
5.	3286	Navaneetha Krishnan	39	M	15/12/2017	10/01/2018	25 Days	Fair
6.	588	Muruganantham	52	M	05/03/2018	31/04/2018	28 Days	Fair
7.	689	Ganeshan	48	M	13/03/2018	13/04/2018	30 Days	Good
8.	723	Krishna Raj	60	M	16/03/2018	10/04/2018	24 Days	Fair
9.	950	Soundararaj	30	M	09/04/2018	08/05/2018	29 Days	Fair
10.	1098	Murugesan	23	M	19/04/2018	17/05/2018	28 Days	Good
11.	1116	Meiyappan	28	M	21/04/2018	20/05/2018	29 Days	Fair
12.	1203	Subburaj	40	M	21/04/2018	21/05/2018	30 Days	Good
13.	1208	Padmanaban	48	M	23/04/2018	13/05/2018	21 Days	Fair
14.	2680	Chellammal	58	F	04/10/2017	14/11/2017	40 Days	Good
15.	3099	Lalitha shenbagam	60	F	21/11/2017	24/12/2017	33 Days	Fair
16.	3240	Mangaiesawari	45	F	11/12/2017	14/01/2018	33 Days	Good
17.	437	Shenbagam	60	F	18/02/2018	10/03/2018	20 Days	Fair
18.	520	Michaelammal	55	F	26/02/2018	26/03/2018	30 Days	Good
19.	1061	Subbammal	33	F	03/04/2018	03/05/2018	30 Days	Good
20.	1068	Shanthi	54	F	03/04/2018	30/04/2018	28 Days	Fair

BIOCHEMICAL ANALYSIS

S.NO	IP.N O	Before Treatment							After Treatment						
		WBC Total cells/ cub.mm	WBC-DC%			ESR		Hb%	WBC Total cells/ cub.mm	WBC-DC%			ESR		Hb%
			P	L	E	½ hr	1 hr			P	L	E	½ hr	1 hr	
1.	2513	6800	58	38	4	-	20	10.9	7200	62	32	6	-	18	11.2
2.	2819	6800	63	33	4	-	20	12.7	6600	68	30	2	-	22	12
3.	3044	5900	51	40	5	-	12	15	6600	61	38	1	-	24	14.6
4.	3047	7100	64	35	1	-	12	13	6900	58	40	2	-	18	13.4
5.	3286	7600	70	27	3	-	20	10.5	7200	68	30	2	-	24	10.8
6.	588	5400	52	47	1	-	30	10.8	5800	60	33	7	-	22	11.2
7.	689	6900	54	38	8	-	30	11	6400	68	26	6	-	18	12.4
8.	723	8000	72	25	3	-	26	12.4	7600	58	38	4	-	16	14
9.	950	7500	58	40	2	-	28	13	7000	68	29	3	-	16	12.7
10.	1098	7000	61	37	3	-	18	14	6600	62	35	3	-	32	13.2
11.	1116	8100	62	31	7	-	30	10.2	6800	65	30	5	-	26	11
12.	1203	7200	60	40	-	-	18	9.8	7000	68	31	1	-	18	10.4
13.	1208	5900	61	38	1	-s	24	15	6200	59	34	7	-	20	14.2
14.	2680	6200	64	34	2	-	18	11.2	7400	62	37	1	-	22	12
15.	3099	6500	64	30	6	-	30	11	6800	58	34	8	-	22	12.5
16.	3240	6400	60	35	5	-	20	11.2	6800	62	34	4	-	18	11
17.	437	6500	64	32	4	-	30	10.4	6700	66	32	2	-	24	11
18.	520	5200	72	25	3	-	34	11	5000	58	40	2	-	28	11.5
19.	1061	5800	58	40	2	-	30	12.4	5400	67	31	2	-	18	12
20.	1068	6000	64	32	4	-	12	10	5800	65	33	2	-	17	10.8

BIOCHEMICAL ANALYSIS

S.NO	IP.NO	Blood sugar		Blood urea (mgs %)		Total cholestrol (mgs %)		Serum creatinine		Bilirubin	
		BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT	BFT	AFT
1.	2513	109	96	18	17	180	162	0.7	0.5	0.5	0.2
2.	2819	88	96	15	22	162	158	0.6	0.7	0.5	0.2
3.	3044	90	104	17	22	122	114	0.7	0.4	0.4	0.2
4.	3047	100	94	20	21	186	165	0.3	0.2	0.5	0.2
5.	3286	72	74	14	16	110	120	0.8	0.7	0.1	0.2
6.	588	116	118	16	15	174	164	0.7	0.5	0.2	0.1
7.	689	124	104	18	17	146	160	0.4	0.2	0.5	0.4
8.	723	132	128	13	20	126	162	0.5	0.3	0.3	0.5
9.	950	84	96	21	19	168	128	0.2	0.1	0.5	0.6
10.	1098	130	116	12	16	203	103	0.9	0.5	0.1	0.2
11.	1116	100	96	11	12	182	128	1.0	0.8	0.6	0.4
12.	1203	104	108	16	16	149	194	0.8	0.4	0.5	0.3
13.	1208	90	100	17	18	122	116	0.7	0.5	0.4	0.2
14.	2680	86	104	22	25	185	172	1.0	0.8	0.2	0.1
15.	3099	86	104	16	20	164	156	0.6	0.2	0.4	0.1
16.	3240	84	96	28	20	190	186	0.4	0.2	0.5	0.4
17.	437	84	90	16	20	171	117	0.5	0.3	0.6	0.2
18.	520	125	104	14	18	164	144	0.6	0.4	0.4	0.1
19.	1061	111	120	18	20	182	128	0.3	0.4	0.3	0.1
20.	1068	98	82	12	11	200	161	0.8	0.6	0.1	0.3

URINE ANALYSIS

S.N O	IP.N O	Before Treatment						After Treatment					
		Al b	Sug ar	Pus cells	Epi. cells	RBC' S	Casts/ crystals	Al b	Suga r	Pus cells	Epi. cells	RBC' S	Casts/ crystals
1.	2513	Nil	Nil	few pus	1-2	NAD	NAD	Nil	Nil	1-2 Pus	NAD	NAD	NAD
2.	2819	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
3.	3044	Nil	Nil	1-4	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
4.	3047	Nil	Nil	1-2	0-1	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
5.	3286	Nil	Nil	NAD	0-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
6.	588	Nil	Nil	2-5	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
7.	689	Nil	Nil	2-4	NAD	NAD	NAD	Nil	Nil	0-2	NAD	NAD	NAD
8.	723	Nil	Nil	NAD	0-4	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
9.	950	Nil	Nil	NAD	1-2	0-2	NAD	Nil	Nil	NAD	NAD	NAD	NAD
10.	1098	Nil	Nil	0-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
11.	1116	Nil	Nil	NAD	0-1	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
12.	1203	Nil	Nil	0-4	NAD	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
13.	1208	Nil	Nil	1-2	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
14.	2680	Nil	Nil	NAD	0-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
15.	3099	Nil	Nil	1-4	NAD	0-1	NAD	Nil	Nil	NAD	0-1	NAD	NAD
16.	3240	Nil	Nil	NAD	1-2	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
17.	437	Nil	Nil	1-2	1-2	NAD	NAD	Nil	Nil	0-1	NAD	NAD	NAD
18.	520	Nil	Nil	NAD	NAD	NAD	NAD	Nil	Nil	NAD	NAD	NAD	NAD
19.	1061	Nil	Nil	2-5	NAD	NAD	few crystals	Nil	Nil	NAD	0-1	NAD	NAD
20.	1068	Nil	Nil	NAD	0-2	1-2	NAD	Nil	Nil	NAD	NAD	NAD	NAD

CHAPTER V

DISCUSSION

My clinical study is “To evaluate the therapeutic efficacy of Open Labelled Randomized trial drug of “**SIRU NERUNJIL KUDINEER**” (Internal) in the treatment of KALLADAIPPU (Urolithiasis). Out of 20 out patients and 20 in patients were selected based on clinical features and modern investigations parameters and siddha diagnostic methods (Envagai Thervugal) were carried out after the disease. It is confirmed by ultrasonogram. The trial drug “**SIRU NERUNJIL KUDINEER**” was prepared and given to the patients. The blood, urine samples and other general details were collected from the patients before and after treatment. The urolithiasis symptoms score of each patient before and after treatment were compared to assess the therapeutic value of the trial drug “**SIRU NERUNJIL KUDINEER**”.

AGE

In this study, among the 20 out-patients, Kalladaippu noi was most common in Pitha Kaalam 34-66 years (60%). and among the 20 in-patients, it was predominant (70%) in Pitha Kaalam 34-66 years.

SEX

From the study, among the 20 outpatients (50%) were Male and (50%) were Female. Whereas among inpatients majority of them were Males (65%) and (35%) were Female cases.

OCCUPATION

From the data collected during the enrollment of patients it was learnt that 30% of the outpatients were House Wives, and 30% of the inpatients were Sedentary Workers.

DIETARY HABITS

Out of the 40 cases who were recruited for the study majority of them (85% of outpatients and 80% of inpatients) were taking Both Vegetarian and Non-Vegetarian items.

MARITAL STATUS:

From the data collection, among the 40 patients majority of them (75% of out patients and 85% of in patients) were Married.

PERSONAL HABITS

From the history taken from the patients it was noted that 75% of outpatients and 60% inpatients does not have any Bad Habits. 25% of outpatients and 40% inpatients have Alcoholism, Smoking, Alcohol with Smoking.

PARUVAKAALAM

In General, Kalladaippu Noi occurs in all the seasons. But in the present study, it was found to be the commonest during Ilavenil Kalam (30% outpatients 30% of inpatients) were affected.

THINAI

Among the patients who were selected for the trial 65% of the outpatients and 80% of the inpatients were from Marutha Nilam. 35% of outpatients were from Neithal Nilam, and 20% of inpatients were from Neithal Nilam.

THEGI (CONSTITUTION OF BODY)

In this study, Vatha Thegi patients were found to be the most affected by Kalladippu noi (60% of outpatients and 65% of inpatients), The second major were Pitha Thegi (30% of outpatients and 20% inpatients). Only a few of them (10% of outpatients and 15% of inpatients) were Kabam Thegi.

MANO THATHUVAM (GUNAM)

In this study, Rajo Gunam patients was affected by Kalladaippu noi (80% of out patients and 70% of in patients). The second major were Sathuva Gunam (15% of out patients and 15% of in patients). Only few of them (5% of out patients and 15% of in patients) were Thamo Gunam.

UYIR THATHUKAL

A. DERANGEMENT OF VATHAM

In the contemporary study, it was noted that all the patients under treatment had disturbances in Abaan and Saman (100%) which was the primary cause for oliguria, dysuria and formation of calculi. Pran was affected in 5% of outpatients and 10% of inpatients has cold and cough experienced by the patients. Derangement in Dhevathathan (10% of outpatients and 15% of inpatients) causes tiredness in the patients, and disturbances in Nagan resulted in (10% of outpatients and 20% inpatients). Derangement in Koorman was affected in 25% of inpatients.

B. DERANGEMENT OF PITHAM

It was noted that Sadhaga Pitham was affected in 80% of outpatients and 60% of inpatients resulting in power to complete the task and difficulty in their regular work in day to day life. Ranjaga Pitham was found to be disturbed in 5% of outpatients and 15% of inpatients.

C. DERANGEMENT OF KAPAM

Santhigam was found to be affected in 5% of outpatients and 15% of inpatients, causing joint pain in elderly patients.

UDAL THATHUKKAL

Among the patients selected for the study Saaram (50% of out patients and 30% of in patients) was affected causing sluggishness. Moolai thaathu was found to be affected in 40% of outpatients and 30% of inpatients and they suffered from Oliguria. Enbu Thathu was found to be affected in (10% of out patients and 30% of inpatients) due to joint pain. Senneer was found to be affected in 15% of outpatients and 30% of inpatients.

KOSANGAL

Among the 40 patients, Annamayakosam (100%) was affected in all patients due to Udal Thathukal. Pranamayakosam was affected in (5% of out patients and 10% of in patients) due to Pran i.e cold and cough.

14 VEGANGAL

Among the 40 cases, controlling of Siruneer (100%) was affected in all patients leads to Oliguria, Dysuria and Haematuria. Controlling of Thummal was affected in few cases (10% of out patients and 15% of in patients) leads to Oliguria

ENVAGAI THAERVUGAL

In this study, Moothiram (100%) was affected in all the patients. Naa was affected in (5% of outpatients and 15% of inpatients) have fissures, pallour in their tongue. Vizhi was affected in (25% of in patients) due to visual disturbances. Vatha Pitha Naadi was felt in most of the patients (60% of outpatients and 50% of inpatients).The second major type of Naadi was Pitha Vatha Naadi (35% of outpatients and 45% of inpatients).It was noticed that only 5% of the outpatients 5% of the inpatients had Vatha Kabha Naadi. and 5% of inpatients affected by Pitha Kabha Naadi.

NEERKURI

It was noted that the urine colour was Yellowish (65% of outpatients and 75% inpatients) and Yellowish Red in (10% of out patients and 5% of in patients), it was normal in 15% of outpatients and 10% of inpatients. Nurai normal in all the patients. Edai was affected in all the 40 patients (100%) due to Haematuria, Dysuria, and mixed with Calculus. Maanam was affected in all the patients (100%) due to Fleshy, Charred ,Ketotic Odour. Enjal was affected in (40% of out patients and 30% of in patients) due to Oliguria, Haematuria.

NEIKURI

When Neikuri was tested in the urine samples of the patients it was observed that majority of them (45% of outpatients and 40% of inpatients) revealed that Vatha Neer. (30% of outpatients and 45% of inpatients) were Pitha Neer. (25% of out patients and 15% of in patients) were Kapha Neer.

DURATION OF ILLNESS

Majority of the patients experienced symptoms of Kalladaippu noi only in the past 2-6 months period (35% of outpatients and 40% of inpatients) and 6 months – 1 year (30% of outpatients and 20% of inpatients). (15% of outpatients and inpatients)

suffered from the disease from 1-11/2 years. Less than 2 months (20% of out patients and 25% of in patients) were affected

NUMBER OF STONES

Before treatment majority of them have Single Stone (60% of out patients and 70% of in patients), and Multiple Stones (40% of out patients and 30% of in patients). But after treatment (50% of out patients and 55% of in patients) have Single stone (Reducing in size of the stone) and Multiple Stones (20% of out patients and in patients) were affected.

POSITION OF STONES

The USG reports of the patients have stones which were mostly (40% of outpatients and 45% of inpatients) present in Left Kidney. In Right Kidney calculi were comparatively lesser (30% in outpatients and 35% in inpatients) and (20% of outpatients and 15% of inpatients) had stones in Both Kidneys. In Left Ureter (10% of out patients and 5% of inpatients).

SIZE OF STONES

The USG reports of the cases before treatment showed that majority of the cases (55% of the outpatients and 65% of the inpatients) presented with stone of size 5mm and above. And 4-5mm (30% of out patients and 20% of in patients). And 1-3mm (15% of out patients and in patients) were affected. After treatment (30% of out patients and 25% of in patients) have normal study report and have no symptoms. Thus the Statistics Analysis also considered as SIGNIFICANT $P < 0.0001$.

UROLITHIASIS SYMPTOMS SCORE

From the above study, Before treatment the patients (25% of out patients and 35% of in patients) were Severely affected. And (75% of out patients and 65% in patients) were Moderately affected. After treatment most of the patients (30% of out patients and 25% of in patients) have No Symptoms that is Normal Study and also Relief in Symptoms. And (55% of out patients and 50% of in patients) have Mild scores. And also (15% of out patients and 25% of in patients) have Moderately affected (reducing in stone size and relief in symptoms). Thus the Analysis also considered as SIGNIFICANT $P < 0.0001$.

STONE ANALYSIS

Stones were received from patient at the end of the treatment. Stones were analysed in a well reputed laboratory to determine the composition of stones. The analysis of the stones indicated the presence of calcium oxalate types of whewellite and weddellite. The stone analysis reports of the patients are enclosed as Annexure V.

GRADING OUTCOME OF THE STUDY

The trial medicine selected for the clinical study was **SIRU NERUNJIL KUDINEER** - **40ml** BD Morning & Evening . The present study proved the therapeutic values of the trial medicine which is evident from the Absence of Calculi and Symptoms associated with Kalladaippu Noi in majority of the patients. Good response was noticed in (60% of outpatients and 50% of inpatients) and Moderate response in (40% of outpatients and 50% of inpatients). The good and moderate response of trial drug in treating Kalladaippu noi is attributed to the lithotriptic, diuretic and analgesic effects of the trial medicine.

CHAPTER-VI

SUMMARY

- The aim of the study is “ To Evaluate the Therapeutic Efficacy of the drug “**SIRU NERUNJIL KUDINEER**” in KALLADAIPPU.
- Before initiating the clinical trial, got approval from INSTITUTIONAL ETHICAL COMMITTEE (IEC) in Government Siddha Medical College. Palayamkottai. Tirunelveli. And got approval from INSTITUTIONAL ANIMAL ETHICAL COMMITTEE (IAEC) at SASTRA University, Thanjavur.
- The trial were authenticated, and also done Biochemical Analysis in Govt. Siddha Medical College, Palayamkottai. Tirunelveli.
- The trial drug undergo Physiochemical Analysis at Chennai Testing Laboratory, Chennai. And also Pharmacological Study done at SASTRA University, Thanjavur. Microbial study also done at Malar Diagnostic Centre at Tirunelveli.
- For clinical study, among 40 cases were selected and recruited for the clinical trial, clinical diagnosis made by both Siddha and modern methodology.
- Before initiating the trial informed consent was obtained from the patients.
- The patients were treated for a period of 30 days. The trial medicine selected for internal treatment was **SIRU NERUNJIL KUDINEER** at the dose of 40ml twice a day referred under Siddha literature **GUNAPAADAM MOOLIGAI** Page.no.597.
- Required laboratory investigations were carried out before and after treatment and the concerned data was recorded in the proforma.
- Clinical assessment was done during each visit in OPD Patients (7days once) and the data was noted in the prescribed proforma.
- During the study period there was no event of any adverse reactions owing to the drug and disease.
- The patients were showed good prognosis within a short period, Oliguria and Burning Micturation reduced within 7 days of treatment.
- It is observed that all other signs and symptoms relived at the end of course of treatment with the trial medicine and strict diet restriction.
- From the clinical examination and enquiring the patients, it was noted that stones were broken into fragments and expelled out in the form of sand grains and gravels

with urine. It is evident from the ultrasonographic investigations that the trial medicine helped in disintegrate of the calculus in some patients.

- Statistical Analysis of Urolithiasis Symptoms Score also shows significant $P < 0.0001$.
- Among 40 cases, Good response was noticed in 60% of OPD and 50% of IPD. And Moderate response in 40% of OPD and 50% of IPD.
- In this study, it has been proved that the trial medicine, ***SIRU NERUNJIL KUDINEER*** (*Internal*) is highly effective and economically viable in curing ***KALLADAIPPU NOI***.

CHAPTER VII

CONCLUSION

The following conclusions have been drawn from the A Prospective Open Labeled Randomized Clinical Trial on “The evaluation of efficacy of the trial drug, **(internal)** in **SIRU NERUNJIL KUDINEER** treating **KALLADAIPPU NOI**”, was carried out at the PG Department of Pothu Maruthuvam, Government Siddha Medical College and Hospital, Palayamkottai as my dissertation work.

1. The Ingredients incorporated in the trial medicine helped to cure Kalladaippu Noi by compensating the increased Pitham which is attributed to the Diuretic, Lithotriptic action, Analgesic effect, as mentioned in the various Siddha Literatures - **Annexure I**.
2. The Biochemical Analysis of trial medicine revealed that the presence of various minerals like Calcium, Sulphate, Chloride, Ferrous Iron and Unsaturated Compounds - **Annexure II**.
3. The Physiochemical Analysis of trial medicine shows determination of Total ash, Insoluble ash and Moisture Content it was within acceptable range. It indicates the longer shelf life period. The Microbial test shows Bacteria and Fungi are less contaminated, and pathogens like Salmonella is absent. And other pathogens are lessly present.– **Annexure III**.
4. The Pharmacological Study on trial medicine revealed the Lithotriptic Effect of the trial medicine – **Annexure IV**.
5. The Microbial Analysis showed very sensitive to my trial drug of siru nerunjil kudineer of E.coli, Pseudomonas aeruginosas, Streptococcus Pneumonia, Klebsiella Pneumonia – **Annexure V**.
6. The Ultra Sonogram Reports of some patients Before treatment and After treatment were compared to evaluate the prognosis in patients – **Annexure VI**

7. The Analysis of Stone of the patient revealed that the presence of Calcium Oxalate type of Whewellite and Weddellite - **Annexure VI**
8. Clinically, the trial medicine is free from side effects as no patient experienced side effects during the course of treatment.
9. The result showed Good Response in 60% of OPD and 50% of IPD and Moderate Response in 40% of OPD and 50% of IPD.

The Trial Medicine was found to have Lithotriptic, Diuretic, Analgesic effect, and have properties to compensate the increased Pitham, which is one of the important causes for Kalladaippu Noi. From this study, it has been proved that the trial medicine of **SIRU NERUNJIL KUDINEER** is highly effective in curing KALLADAIPPU NOI.

ANNEXURE I

PREPARATION OF TRIAL MEDICINE

சிறு நெருஞ்சில் குடிநீர் (SIRU NERUNJIL KUDINEER)

சேரும் சரக்குகள்:

சிறு நெருஞ்சில் காய்	-	68 கிராம்
கொத்தமல்லிவிதை	-	8 கிராம்
தண்ணீர்	-	680 கிராம்

செய்முறை:

நெருஞ்சில் காய் மற்றும் கொத்தமல்லி விதை இரண்டையும் காய வைத்து ஒன்றிரண்டாக இடித்து தேவையான அளவு நீர் விட்டு அதை நேர்பாதியாக சுண்டவைத்து வடிகட்டி கொடுத்து வரவும்.

அளவு :

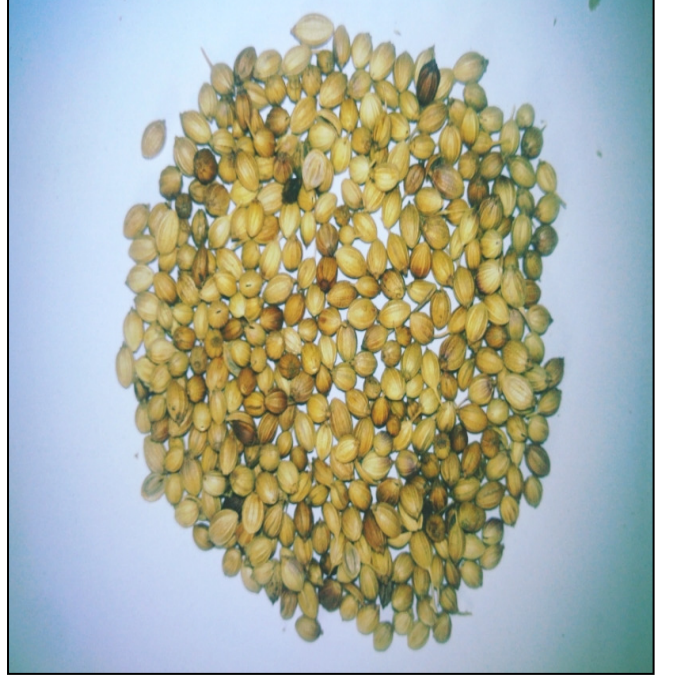
40 மி.லி (இருவேளை)

தீரும் நோய்கள்:

நீரடைப்பு, சதையடைப்பு, கல்லடைப்பு, நீர்ளரிச்சல்



சிறு நெருஞ்சில் காய்



கொத்துமல்லி விதை



சிறு நெருஞ்சில் குடிநீர் பொடி



சிறு நெருஞ்சில் குடிநீர்

PROPERTIES OF THE TRIAL MEDICINE DRUGS

TRAIL MEDICINE : SIRU NERUNJIL KUDINEER.

Ingredients

1. சிறு நெருஞ்சில் காய்
2. கொத்தமல்லி விதை

1. சிறு நெருஞ்சில் காய்: (Tribulus terrestris)

வேறுபெயர் : திரிகண்டம், திரிகண்டகம், திரிதண்டம், கோண்டம், சுவதட்டம் அசுவசட்டிரம், சுவாதுகண்டம், நெருஞ்சிபுதம், காகரசி, கதலி

English Name: Small Caltrops, Land Caltrops, Punol – ure – vine

Family : Zygophyllaceae

சுவை : துவர்ப்பு, இனிப்பு

செய்கை : குளிர்ச்சியுண்டாக்கி, சிறுநீர்பெருக்கி, உள்ளழலாற்றி, உரமாக்கி, ஆண்மைப்பெருக்கி, துவர்ப்பி.

பொதுகுணம் :

“நல்லநெருஞ்சிலதுநாளுங்கிரிச்சாரத்தை
வல்லசுரமனலைமாற்றுங்காண் - மெல்லியவே!
மாநிலத்தில் கல்லடைப்பும் வாங்காதநீர்க்கட்டும்
கூனுறுமெய் வாதமும் போக்கும்”

தீரும் நோய்கள்:

சொட்டுநீர், கல்லடைப்பு, நீரடைப்பு ,நீரளரிச்சல், சுரவெதும்பல், முக்குற்றம், நீர்வேட்கை, வெப்பம்

2. கொத்துமல்லி விதை: (Coriandrum sativum)

வேறுபெயர் : உருள் அரிசி,தனியா

English Name: Coriander seeds

Family : Umbeliferae

சுவை : கார்ப்பு

செய்கை : பசித்தீத்தாண்டி, அகட்டுவாய்வகற்றி, வெப்பமுண்டாக்கி, சிறுநீர்பெருக்கி

பொதுகுணம் :

“கொத்துமல்லிவெப்பம் குளிர்காய்ச்சல் பித்தமந்தஞ்
சர்த்திவிக்கல் தாகமொடுதாதுநட்டம் - சுத்தியெழும்
வாதவிகார்மடர் வன்கர்த்தபிவிரணம்
பூதலத்தில் லாதகற்றும் போற்று”

தீரும் நோய்கள்:

உட்கூடு, நளிர்ச்சுரம், பைத்தியநோய், செரியாமை, வாந்திவிக்கல், நாவறட்சி, பெருஏப்பம், புண் இவைபோகும்.

ANNEXURE II

BIO-CHEMICAL ANALYSIS OF SIRU NERUNJIL KUDINEER

PREPARATION OF THE EXTRACT

5 gm of drug was weighted accurately and placed in a 250ml clean beaker then 50ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100ml volumetric flask and then it is made up to 100ml with distilled water. This fluid was taken for analysis.

QUALITATIVE ANALYSIS

S. NO	EXPERIMENT	OBSERVATION	INFERENCE
1	<u>TEST FOR CALCIUM</u> 2 ml of the above prepared extract is taken in a clean test tube. To this add 2 ml of 4% ammonium oxalate solution	A White precipitate is formed	Indicates the presence of calcium
2	<u>TEST FOR SULPHATE</u> 2 ml of the extract is added to 5% barium chloride solution	A white precipitate is formed	Indicates the presence of sulphate
3	<u>TEST FOR CHLORIDE</u> The extract is added with silver nitrate solution	A white precipitate is formed	Indicates the Presence of chloride
4	<u>TEST FOR CARBONATE</u> The extract is treated with concentrated HCL	No brisk effervescence is formed	Absence of carbonate
5	<u>TEST FOR STARCH</u> The extract is added with weak iodine solution	No blue color is formed	Absence of starch
6	<u>TEST FOR FERRIC IRON</u> The extract is acidified with glacial acetic acid and add potassium ferrocyanide	No blue colour is formed	Absence of ferric iron

7	<u>TEST FOR FERROUS IRON</u> The extract is treated with concentrated nitric acid and ammonium thiocyanate solution	Blood red colour is formed	Indicates the presence of ferrous iron
8	<u>TEST FOR PHOSPHATE</u> The extract is treated with ammonium molybdate and concentrated nitric acid	No yellow precipitate is formed	Absence of phosphate
9	<u>TEST FOR ALBUMIN</u> The extract is treated with Esbatch's reagent	No yellow precipitate is formed	Absence of albumin
10	<u>TEST FOR TANNIC ACID</u> The extract is treated with ferric chloride	No blue black precipitate is formed	Absence of tannic acid
11	<u>TEST FOR UNSATURATION</u> Potassium permanganate solution is added to the extract	It gets decolourised	Indicates the presence of unsaturated compounds
12	<u>TEST FOR REDUCING SUGAR</u> 5 ml of benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8- 10 drops of the extract and again boil it for 2 minutes	No colour change occurs	Absence of reducing sugar
13	<u>TEST FOR AMINO ACID</u> One or two drops of the extract is placed on a filter paper and dried well. After drying 1% Ninhydrin is sprayed over the same and dried well	No violet colour is formed	Absence of Amino acid
14	<u>TEST FOR ZINC</u> The extract is treated with potassium ferrocyanide	No white precipitate is formed	Absence of zinc

INFERENCE

The given sample of the trail drug *SIRU NERUNJIL KUDINEER* contains **Calcium, Sulphate, Chloride, Ferrous Iron and Unsaturated Compounds.**

ANNEXURE III

PHYSIO CHEMICAL ANALYSIS



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CIN : U74999TN2008PTC067568

TEST REPORT

Report Number and date	CTL/CH/N-2109/2017-18 & 06.07.2017		
Sample Number	N-2109/17-18		
Customer Name & Address	Dr. G. Subash Chandran		
	Govt.Siddha Medical College, Palayam Kottai, Tirunelveli - 627 002.		
SAMPLE DETAILS			
Sample Description By Customer	Herbal Powder		
Quantity Received	100 g	Sampled By	Customer
Date of Receipt	28.06.2017	Sample Condition	Good & Received in Packed Condition
Analysis Starting Date	29.06.2017	Analysis Completion Date	06.07.2017

Test Results:

The above sample tested as received, and results are as follows:

S. NO	PARAMETERS	METHOD	UNITS	RESULTS
1	Colour	Organoleptic analysis	-	Pale Greenish
2	Odour		-	Mild Aromatic
3	Taste		-	Mild Sour
4	Loss on drying @ 105 C	AOAC 19th Edn 2012, 964.25	%	6.71
5	Total Ash	IS 1797 : 1985 RA.2009	%	5.10
6	Acid Insoluble ash		%	0.70
7	pH @ 10 % aq.solution	IS 12711 : 1989 RA.1994	-	5.44
8	Water Solable Extract	IS 1797 : 1985 RA.2009	%	12.4
9	Calcium as Ca	IS 5949 : 1990 RA.2003	mg/100g	587
10	Phosphorous as P	AOAC 19th Edn 2012, 995.11	mg/100g	10.6
11	Zinc as Zn	AOAC 19th Edn 2012, 999.11	mg/100g	1.88
12	Chromium as Cr	CTL/SOP/FOOD/096-2014	mg/kg	BDL(DL:0.5)
13	Lead as Pb		mg/kg	1.13
14	Cadmium as Cd		mg/kg	BDL(DL:0.1)
15	Mercury as Hg		mg/kg	BDL(DL:0.1)
16	Arsenic as As		mg/kg	BDL(DL:0.1)
Microbiology:				
17	Total Bacterial Count	IS 5402 : 2012	CFU/g	48000
18	Total Fungal Count	IS 5403 : 1999	CFU/g	700
19	<i>E.coli</i>	IS 5887 Part 1. 1976 RA.2005	CFU/g	< 10
20	<i>Salmonella</i>	IS 5887 Part 3. 1999	per 25g	Absent
21	<i>Staphylococcus aureus</i>	IS 5887 Part 2. 1996 RA.2005	CFU/g	250
22	<i>Pseudomonas</i>	CTL/SOP/MICRO/032-2015	CFU/g	< 10

BDL - Below Detection Limit; DL - Detection Limit

END OF REPORT

For Chennai Testing Laboratory Pvt Ltd

The Report shall not be used to malign, defame and for any malicious purpose.
The Report is meant only for sole use of the addressee to promote his/her own business.

A - Super 19 | T.V.K. Industrial Estate | Guindy | E-mail : chennaitestinglab@gmail.com
Chennai - 600 032 | Tamil Nadu | India | Telefax : +91-44-2250 1757

Page 1 of 1

Interpretation:

The Total ash value, Insoluble ash, and Water soluble extract, Moisture content it was within acceptable range. It indicates the longer shelf life period. The amount of minerals and earthy materials present in the drug material.

The total bacterial count, and the total fungal count of the drug were found that the drug is less from microbial contamination. The other pathogens like Salmonella is absent, Escherichia coli, Staphylococcus aureus, Pseudomonas are lessely present.

	<h1>CARISM - SASTRA</h1>		
	<h2>TOXICOLOGY REPORT</h2>		
Report No	Issue Date		Page 1 of 9
CARISM/CAF/TOX/CAF/S/168/2018-05	05.07.2018		

TOXICOLOGY REPORT

Report Date : 05.07.2018

SR No. : CAF/S/168

Sample ID No. : 246

Sample Name : SIRO Nerungil Kudineer

Identification and condition of the test item : Samples received in good condition

Test item received on : 09.03.2018

Sample description : Powder

Report prepared on : 03.07.2018



Name & address of the customer : Ms.Seethalakshmi
Govt. Siddha College
Palayamkottai.

Name & Address of the Testing Laboratory
Central Animal Facility, SASTRA Deemed University, Thanjavur - 613 401.
Email : panchapakesan@sastra.edu
Phone : +914362-264101-108 Extn. 3680
Fax : +914362-264120

*This report contains nine pages and this report shall not be reproduced
except in full without the written approval of the laboratory.*

Analysed by 
Deputy Technical Manager-Toxicology

Authorised by 
Technical Manager

	<h1>CARISM - SASTRA</h1>		
	<h2>TOXICOLOGY REPORT</h2>		
Report No	Issue Date		Page 2 of 9
CARISM/CAF/TOX/CAF/S/168/2018-05	05.07.2018		

Methods


1. Standard procedure for Euthanasia & Necropsy as per CARISM/SOP/CAF/01
2. Standard procedure for Receipt, Handling and Preparation of test Substance as per CARISM/SOP/CAF/05
3. Standard procedure for Route of Administration in animals as per CARISM/SOP/CAF/06
4. Standard procedure for Animal Handling as per CARISM/SOP/CAF/07
5. Standard procedure for Animal Identification as per CARISM/SOP/CAF/08
6. OECD Guidelines for the Testing of Chemicals "Acute Dermal Toxicity-402" OECD Publishing, Paris. Adopted: 24 Feb 1987

Analysed by





Deputy Technical Manager-Toxicology

Authorised by



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	<h1 style="text-align: center;">CARISM - SASTRA</h1>		
	<h2 style="text-align: center;">TOXICOLOGY REPORT</h2>		
Report No CARISM/CAF/TOX/CAF/S/168/2018-05	Issue Date 05.07.2018	Page 3 of 9	

TEST SYSTEM

Test Species : *Rattus norvegicus*
Strain : Wistar rats
Age : Healthy young adult animals between 8 and 12 weeks
Source : Central Animal Facility, SASTRA Deemed University
Number of Animals : 30
Dose : 37.5, 75 and 150 mg/kg body weight
Route of administration : Oral

Acclimatization

Seven days prior to the experiment.

Identification and treatment details of Animals

Tags marked with animal number, group number and dose level were attached to the respective cages. Each animal was identified by unique identification number by ear tagging.

Group	Group Description	Number of animals	Animal ID	Treatment details
I	Normal control	6	10353-10358	Distilled water only
II	Diseased control	6	10359-10364	Distilled water + Ethylene glycol (0.75%) in drinking water
III	Lower dose	6	10365-10370	Ethylene glycol (0.8%) + Nerungil kudineer (37.5 mg/kg. B wt. po)
IV	Medium dose	6	10371-10376	Ethylene glycol (0.8%) + Nerungil kudineer (75 mg/kg. B wt. po)
V	Higher dose	6	10377-10382	Ethylene glycol (0.8%) + Nerungil kudineer (150 mg/kg. B wt. po)

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	<h1>CARISM - SASTRA</h1>		
	<h2>TOXICOLOGY REPORT</h2>		
Report No		Issue Date	Page 4 of 9
CARISM/CAF/TOX/CAF/S/168/2018-05		05.07.2018	

ANIMAL HUSBANDRY

Animal House Condition

Temperature of the test room was maintained between $22\pm 3^{\circ}\text{C}$ and relative humidity between 50 to 70 % during the experimental period. The experimental room was provided with a 12h light and 12h dark lighting condition using an automatic timer.

Housing

Standard polypropylene rat cages with stainless steel top grill was used to house the animals. The cages were autoclaved. Sieved and sterilized paddy husk was used as the bedding material. Animals were housed individually.

Sanitation

Bedding material, cages, grills and water bottles were changed weekly twice.

Animal Welfare and Regulatory Compliance

The experiment was conducted at the Central Animal Facility registered (No. 817/PO/ReRc/S/04/CPCSEA dated 20.11.2015) for Breeding and Experiments of Animals by the Committee for the Purpose of Control and Supervision of Experiments on Animals, Ministry of Forest and Environment, Govt. of India.

The study was conducted after the approval by the Institutional Animal Ethical Committee, SASTRA University (IAEC Approval Number: 483/SASTRA/IAEC/RPP).

Diet and Water

Standard rodent pellet feed supplied by M/s. ATNT Laboratories, Mumbai, India and Reverse Osmosis (RO) water were provided to the animals *ad libitum*.

Preparation of Test Substance

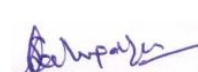
The freshly prepared decoctions were orally administered to the experimental rats as mentioned above.

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	<div>CARISM - SASTRA</div> <div>TOXICOLOGY REPORT</div>		
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Experimental procedure

- Male Wistar rats were divided into five groups of six each.
- Urolithiasis in rats was induced by treating with 1% ammonium chloride plus 0.4% ethylene glycol for first week followed by 0.8% ethylene glycol alone up to 21 days in normal drinking water except Group 1
- Groups III to V served as curative regimen and test drug was administered orally from 15th day till 28th day.
- On 28th day, urine samples were collected using metabolic cages for 24 hours and the volume of urine was measured.
- The urine samples were analysed for calcium and phosphorus.
- On 28th day, blood was collected from the retro-orbital under anesthetic conditions and the serum was separated by centrifugation at $10,000 \times g$ for 10 min and was analyzed for urea, calcium, uric acid and Phosphorus.
- On 28th day, after blood collection, animals were sacrificed and the kidneys were isolated from each animal.
- Isolated kidneys were cleaned off extraneous tissue and preserved in 10% neutral formalin and processed for histopathological studies.

Statistical Analysis

The values are represented as mean \pm SD. Statistical differences between the treatments and the controls were tested by one-way analysis of variance (ANOVA) followed by the Tukey's multiple comparisons test using the "GraphPad prism 5". A difference in the mean values of $p < 0.05$ was considered to be statistically significant.

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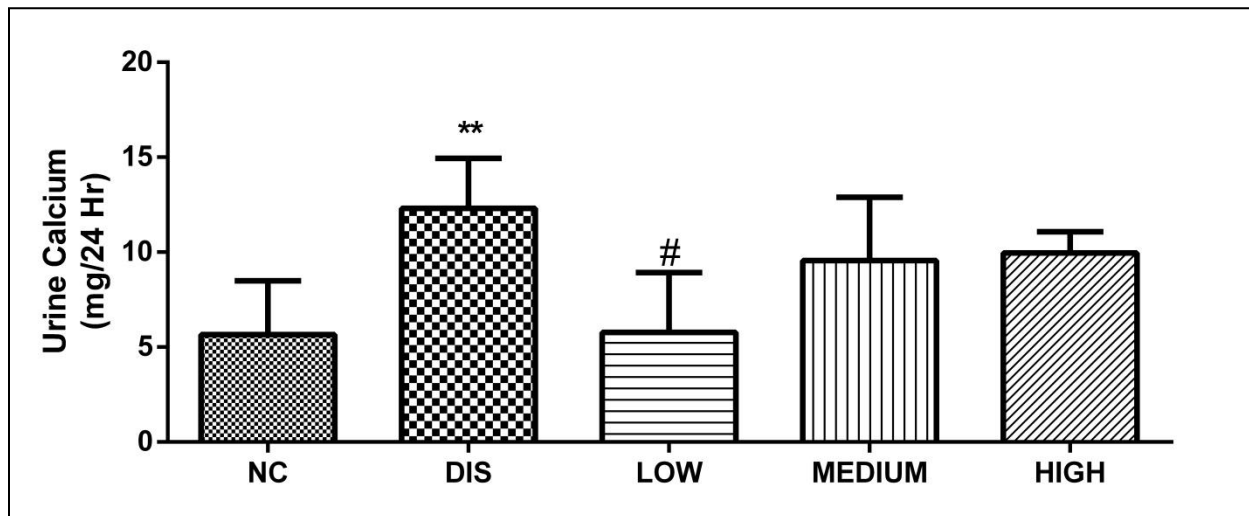
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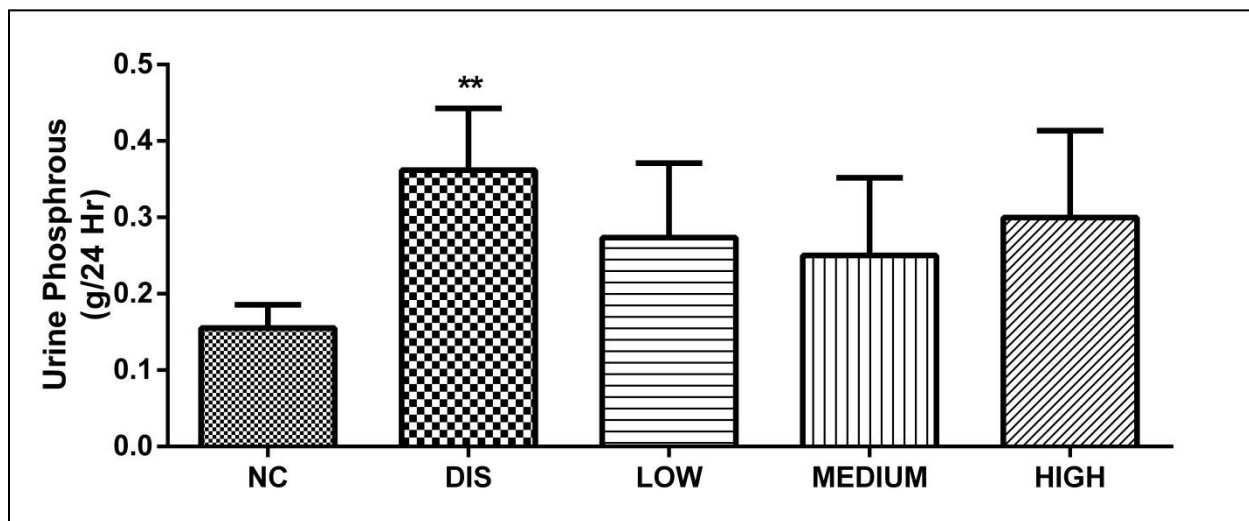
OBSERVATIONS

Effect of test substance (246) on urine calcium level



Values expressed as Mean \pm SD, Statistical analysis was performed using ANOVA followed by the Tukey's test ** $p < 0.01$ Vs Normal control, # $p < 0.05$ Vs Disease control.

Effect of test substance (246) on urine phosphorus level



Values expressed as Mean \pm SD, Statistical analysis was performed using ANOVA followed by the Tukey's test ** $p < 0.01$ Vs Normal control.

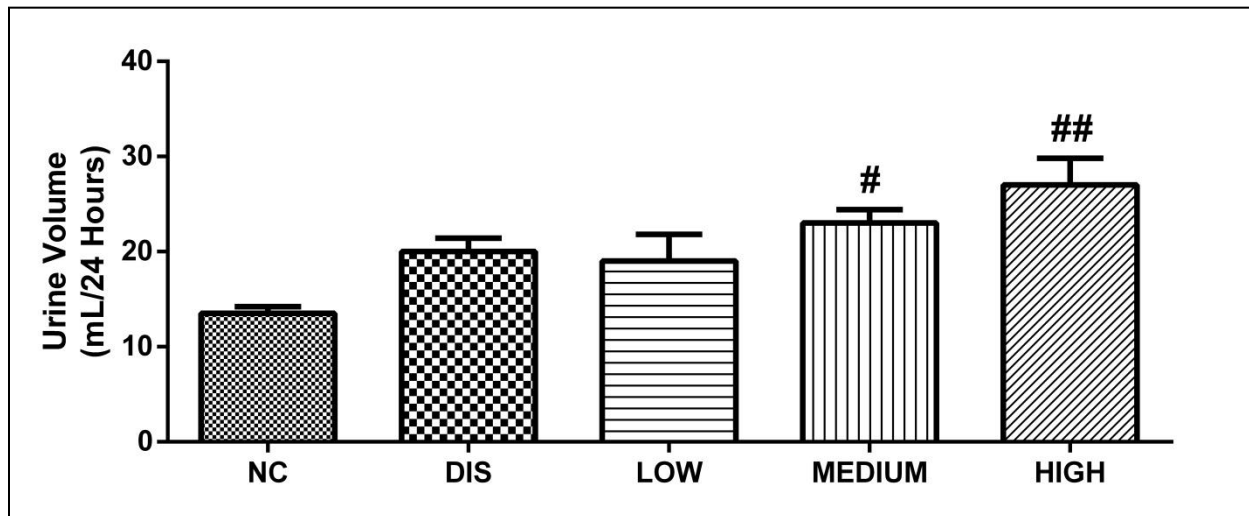
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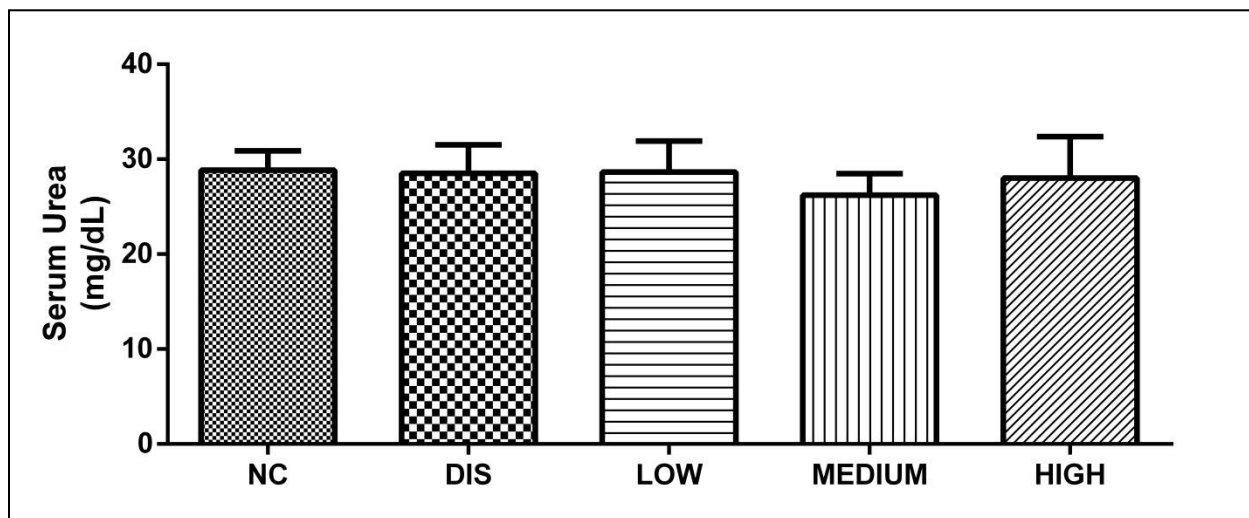
Technical Manager

Effect of test substance (246) on urine volume



Values expressed as Mean \pm SD, Statistical analysis was performed using ANOVA followed by the Tukey's test ^{##}p<0.01, [#]p<0.01 Vs Disease control.

Effect of test substance (246) on serum urea level



Values expressed as Mean \pm SD.

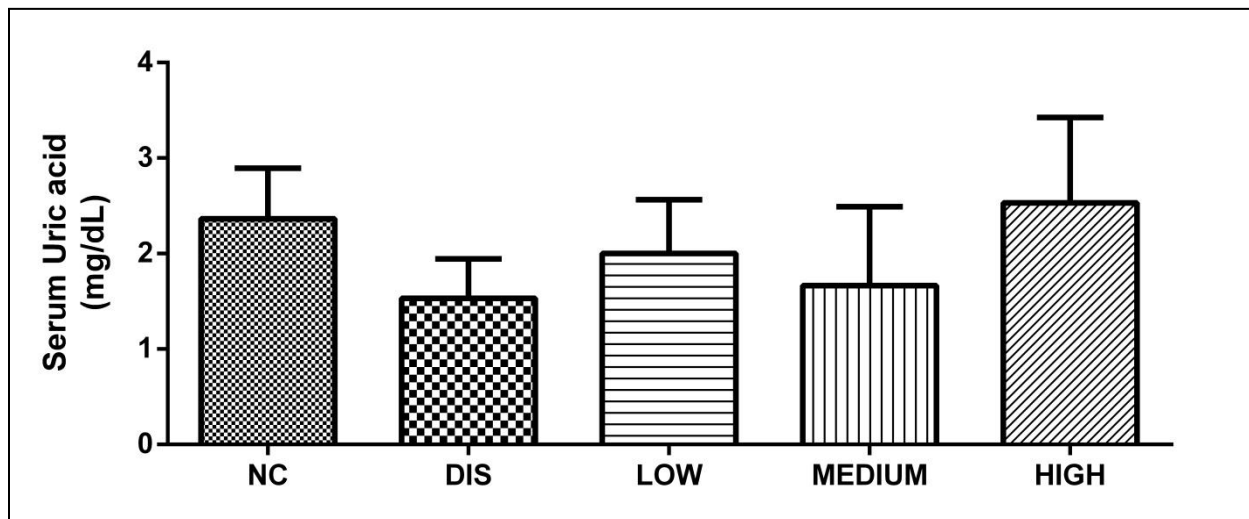
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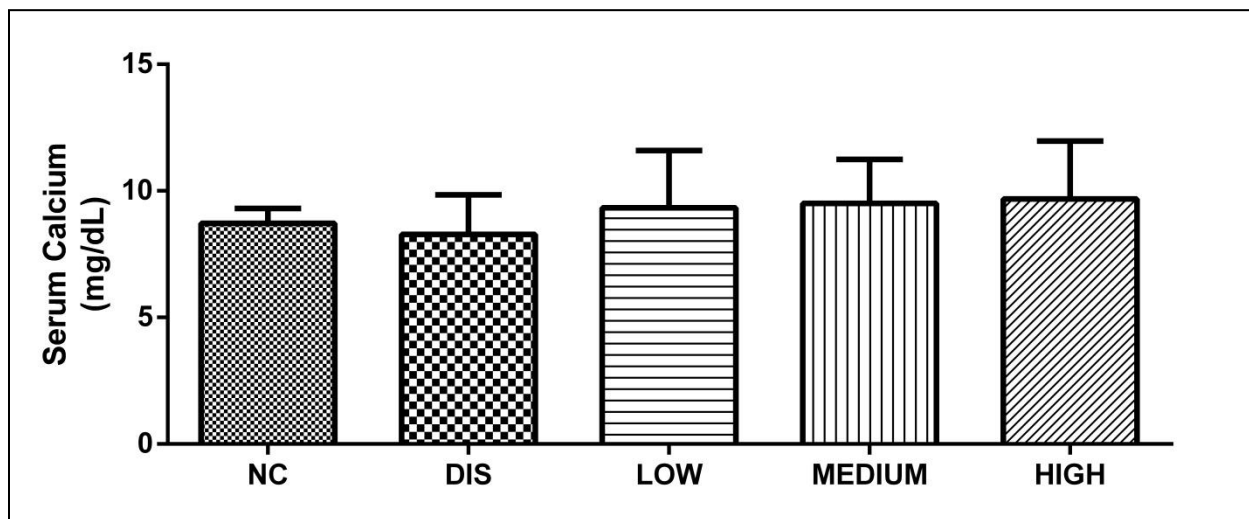
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Effect of test substance (246) on serum uric acid level



Values expressed as Mean \pm SD.

Effect of test substance (246) on serum calcium level





Values expressed as Mean \pm SD.

Analysed by 

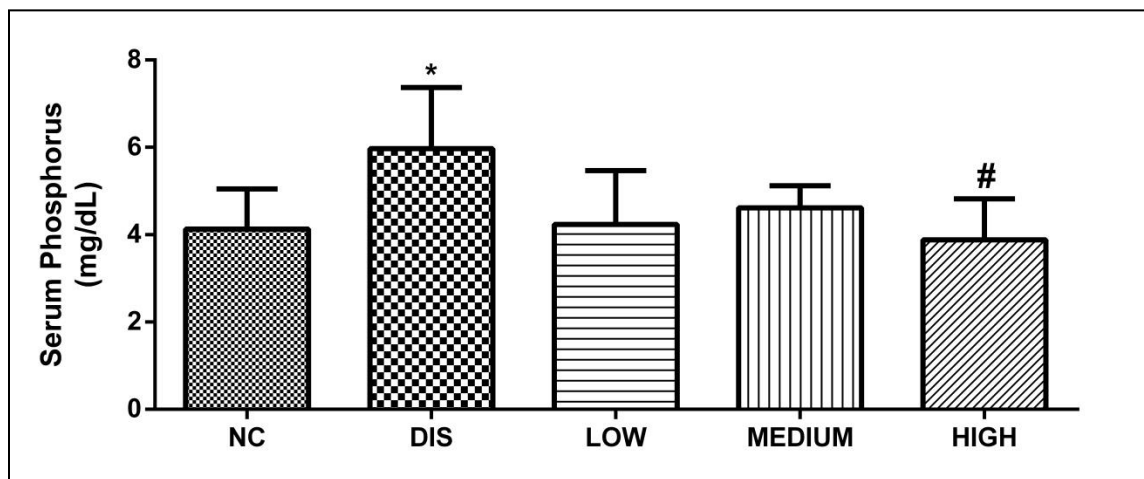
Deputy Technical Manager-Toxicology

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<div>Report No</div>	<div>Issue Date</div>		<div>Page 9 of 9</div>
<div>CARISM/CAF/TOX/CAF/S/168/2018-05</div>	<div>05.07.2018</div>		

Effect of test substance (246) on serum phosphorus level



Values expressed as Mean \pm SD, Statistical analysis was performed using ANOVA followed by the Tukey's test, * $p < 0.05$ Vs Normal control, # $p < 0.01$ Vs Disease control.

RESULTS

- Disease control group shows significant ($p < 0.01$) increase in urine calcium level compared with normal control animals, whereas after treatment with test substance (246) showed significant ($p < 0.05$) decrease in urine calcium level compared with disease control animals.
- The experimental rats treated with ethylene glycol alone (Group 2) showed significant ($p < 0.05$) increase in urine phosphorus level, whereas rats treated with test substance (246) showed decrease in phosphorus level but not significant.
- Urine volume: Urolithiasis rats treated with test substance (246) showed dose dependent increase in urine volume compared with normal and disease control. This indicates that the test substance is possessing diuretic effect.
- No significant changes were observed in serum calcium, urea and uric acid levels in rats treated with test substance (246).
- Significant ($p < 0.05$) increase in serum phosphorus level was observed in disease control group, whereas rats treated with test substance (246) at the dose level 150 mg/kg b wt. showed significant ($p < 0.05$) decrease in serum phosphorus level compared with disease control group.

Analysed by 

Deputy Technical Manager-Toxicology

Authorised by 

Technical Manager

Annexure -V

MICROBIOLOGICAL ANALYSIS OF SIRU NERUNJIL KUDINEER

By Kirby – Bauer method

Aim

To determine the anti-microbial activity of “ **Siru Nerunjil Kudineer** ”.

Components of Muller Hinton Agar Medium

Beef extract	-	300 grams/liter.
Agar	-	17 grams/liter.
Starch	-	1.5 grams/liter.
Casein hydroxylate	-	17.5 grams/liter
Distilled Water	-	1000ml.
Ph	-	7.6.

Procedure

The method of antimicrobial activity study is UPs Diffusion method.

Antibiotic discs are prepared with known concentration of antibiotic are placed on Agar plates that has been inoculated with the known pathogenic microorganism.

The antibiotic diffuses through the agar producing an anti-biotic concentration; gradient anti-microbial susceptibility is proportional to the diameter of the inhibitory zone around the disc. If the micro organism which grows up to the edge of the disc are resistant to the antimicrobial agent.

The recommended medium in this method is Muller Hinton Agar, its PH should be between 7.2 – 7.6 and should be poured to uniform thickness of 4mm in the petri plate (25ml).

Methodology

Muller Hinton Agar plates are prepared and (*Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*) are inoculated separately.

The prepared discs of *Nerunjil Kudineer* are placed over the incubated plate.

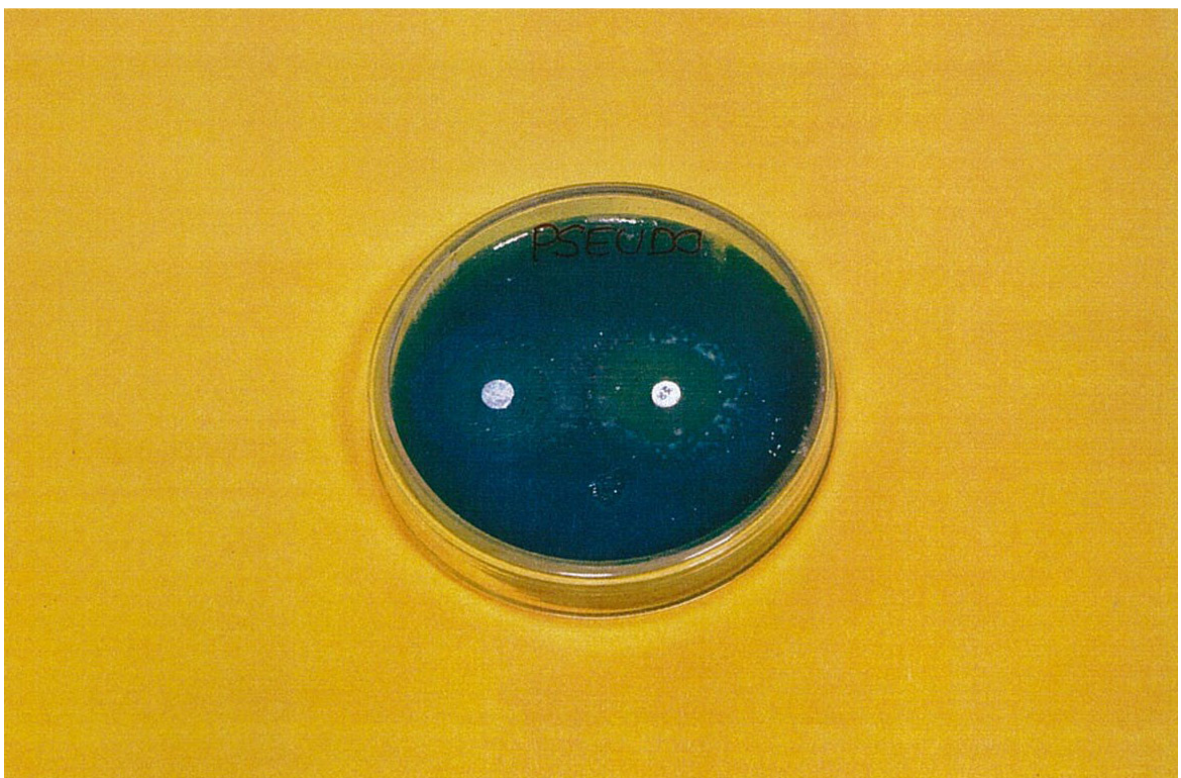
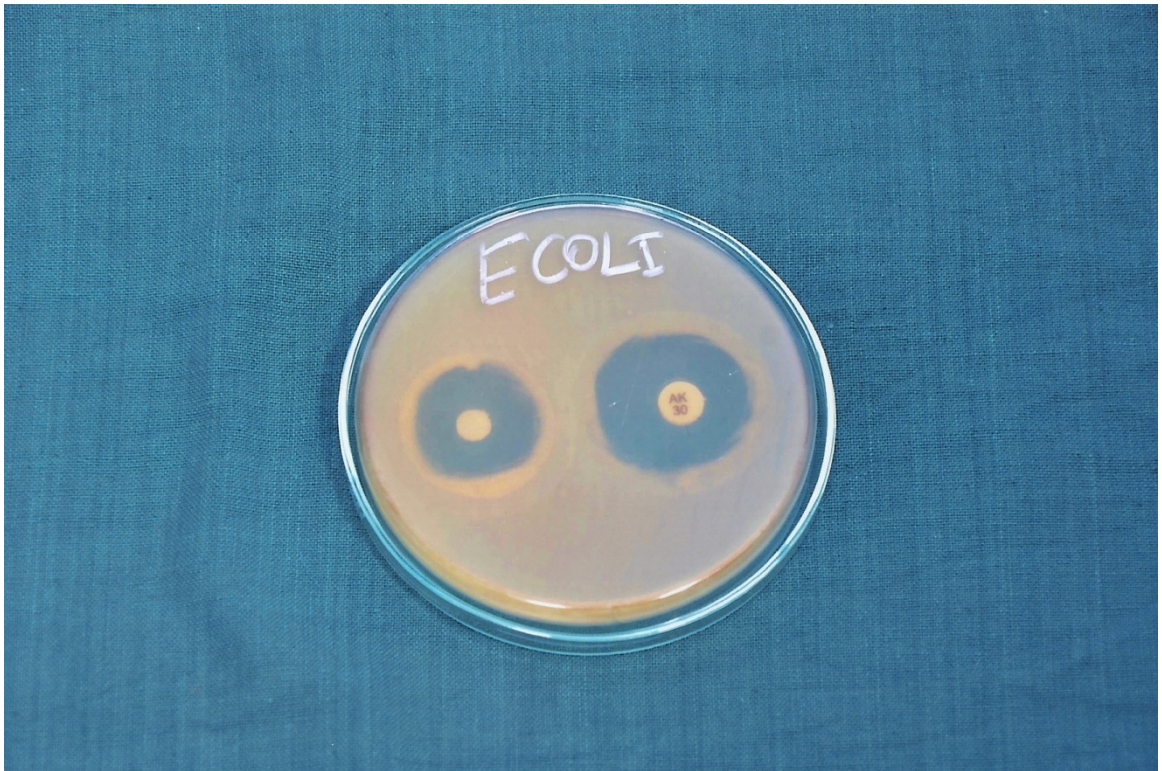
Using sterile forceps and incubated for 24 hours at 37°C. The plates after 24 hours incubation are observed for the zone of inhibition.

Result

Sl.No	Test Drug	Organism (Culture)	Control Zone size	Test Zone Size	Susceptibility
1	SIRU NERUNJIL KUDINEER	<i>Escherichia coli</i>	20mm	17 mm	Sensitive
2		<i>Klebsiella pneumoniae</i>	15mm	13 mm	Moderate Sensitive
3		<i>Pseudomonas aeruginosa</i>	19mm	18 mm	Sensitive
4		<i>Streptococcus pneumoniae</i>	15mm	14 mm	Sensitive

Report

Siru Nerunjil Kudineer is sensitive to *Escherichia Coli*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*. Moderately sensitive to *Klebsiella pneumoniae*.



,



Name :	MR. AJANTHAN. R	Age/Sex :	37Y/M
Branch :	TIRUNELVELI-VPI	SID No :	16038370 -R
Ref. By :	Dr. GOVT.SIDDHA MEDICAL COLLEGE	SID Date :	09/06/2017
USG ABDOMEN			

LIVER:

Is normal in size and uniform in echo texture.
 Intrahepatic biliary radicles and CBD appear normal.
 Portal and hepatic veins appear normal.

GALL BLADDER:

Contracted (Post prandial status). No internal echoes are seen. Wall thickness is normal.

PANCREAS:

Obscured by bowel gas.

SPLEEN:

Is normal in size and uniform echogenicity.

KIDNEYS:

RT. Kidney measures 9.7 x 4.8cms.

LT.Kidney measures 10.1 x 4.5cms.

A calculus of size 4mm seen in upper pole of left kidney.

Cortico medullary differentiation is maintained on both sides.
 Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal contour. No intra luminal echoes are seen. Urinary bladder wall thickness is normal.

PROSTATE:

Measures 3.6 x 3.1 x 3.0cms. Vol: 18.3cc.

RIF:

Appears normal. No free fluid.

IMPRESSION:

- ❖ Left renal calculus.
- ❖ Normal sonographic study of Liver, Spleen, Right Kidney, Bladder and Prostate.

DR.T.ANNIE STALIN
CONSULTANT SONOLOGIST.

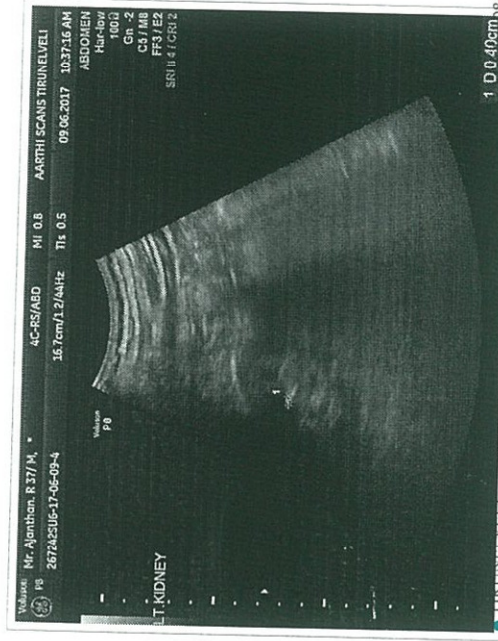
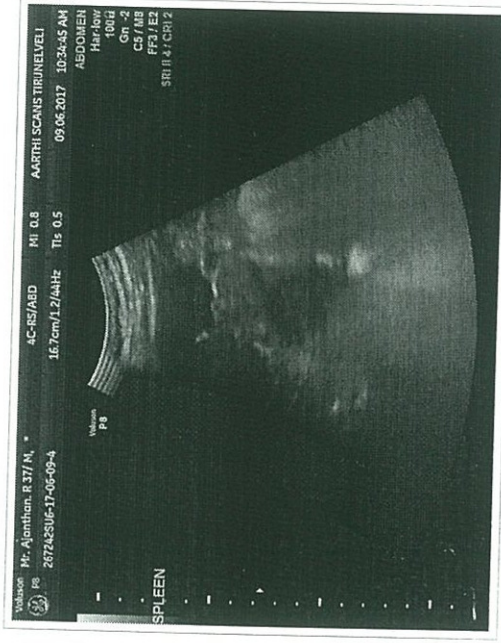
• TIRUNELVELI : 177, TVM Road, Vannarapettai, Ph:0462-2501353, Mobile : 98430 40346 • THANJAVUR : 22/1, Pudukottai Rd, Ph:279914,279917, Mobile:87544 38504, 99529 69814
 • PALAYAMKOTTAI: Lakshmi Complex, North High Ground Road, Ph : 0462-258 1353 • TENKASI : 242, Samba Street, Ph:04633-223211, Mobile : 99401 60517
 • TUTICORIN :40, Palai Road, Ph : 0461 - 232 7353, Mobile : 99401 10515 • KOVILPATTI : 14-D, Santhai Pettai Road, Ph:04632-228626, Mobile:99400 22448
 • MADURAI : 4, Dr. Thangaraj Salai, Madurai Ph:0452-2521353, Mobile:99400 80507 • RAJAPALAYAM: 64, Kamaraj Nagar, 2nd Street, Ph:04563-225101,Mobile:99401 10504

Note : This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters

Name \ ID Mr. Ajanthan. R 37/ M \ 267242SU6-17-06-09-4 Age / Sex 0 / 0

Visit Date 9-6-2017

Ref.Doc --



- PALAYAMKOTTAI: Lakshmi Complex, North High Ground Road, Ph: 0462-258 1353
- TUTICORIN :40, Palai Road, Ph : 0461 - 232 7353, Mobile : 99401 10515
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Note : This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters

Name	DR.AJANTHAN. R	Patient ID	AS_VPI_US_14806
Accession No	16_014806_182267	Age/Gender	37Y / Male
Referred By	Dr.GOV.T.SIDDHA MEDICAL COLLEGE	Date	17-Mar-2018

USG ABDOMEN

LIVER:

Is normal in size and uniform in echo texture.

Intrahepatic biliary radicles and CBD appear normal. Portal and hepatic veins appear normal.

GALL BLADDER:

Is adequately distended. No internal echoes are seen. Wall thickness is normal.

PANCREAS:

Appears normal in size and it shows uniform echo texture.

SPLEEN:

Is normal in size and uniform echogenicity.

KIDNEYS:

RT. Kidney measures 7.9 x 4.2cms. LT.Kidney measures 9.1 x 4.1cms.

Cortico medullary differentiation is maintained on both sides.

Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal contour. No intra luminal echoes are seen. Urinary bladder wall thickness is normal.

PROSTATE:

Measures 3.5 x 3.4 x 3.4cms. Vol: 21.7cc.

RIF:

Appears normal. No free fluid.

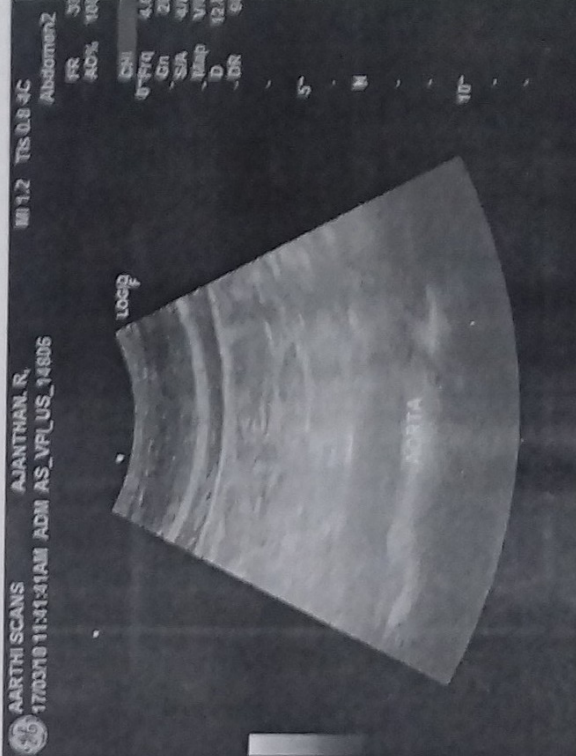
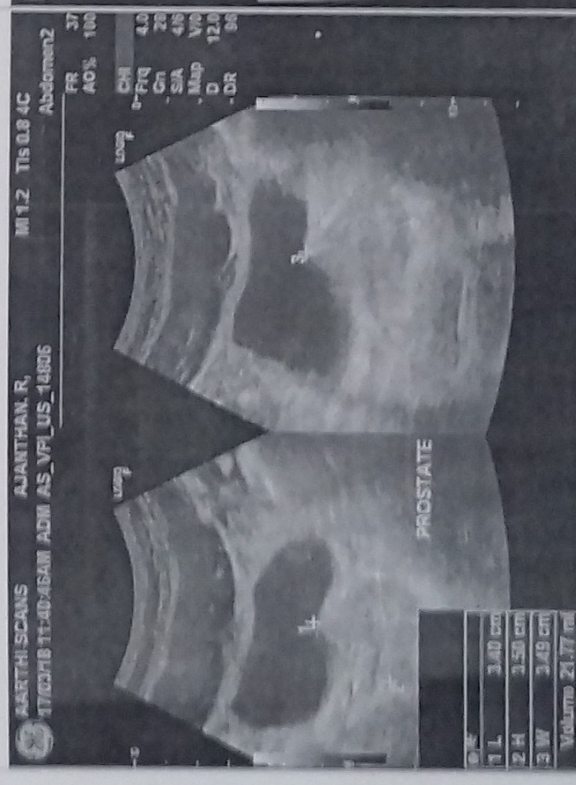
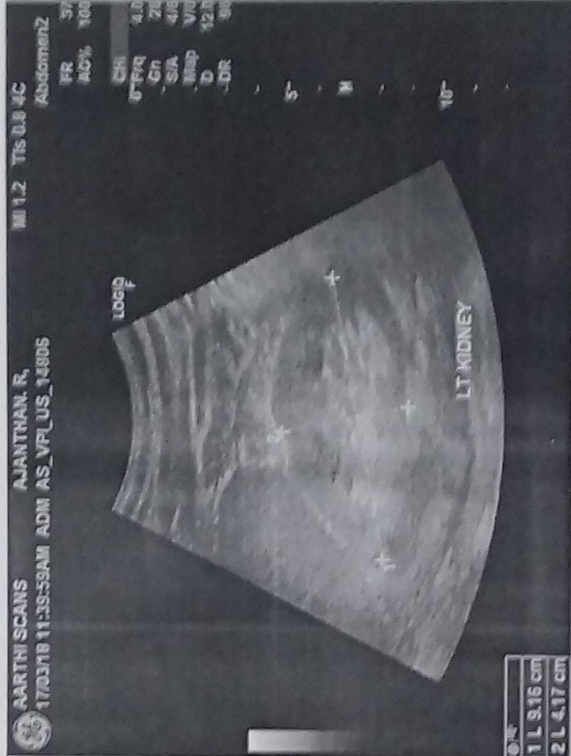
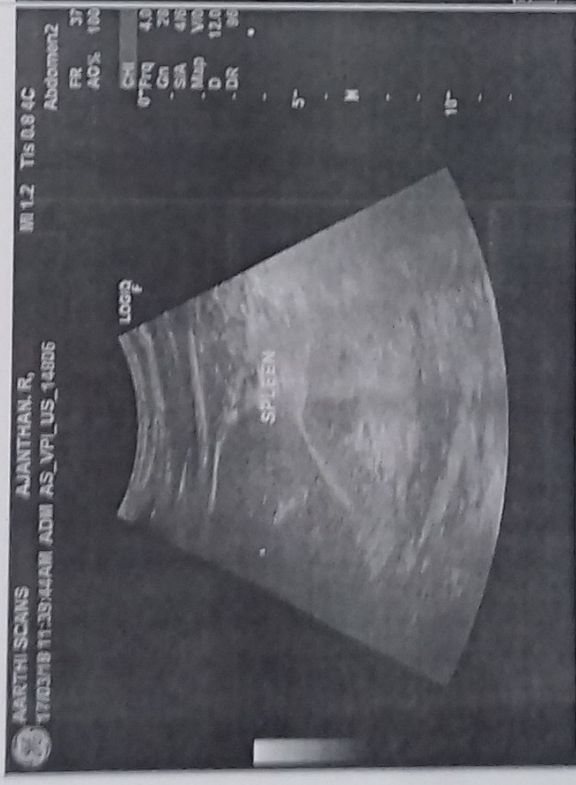
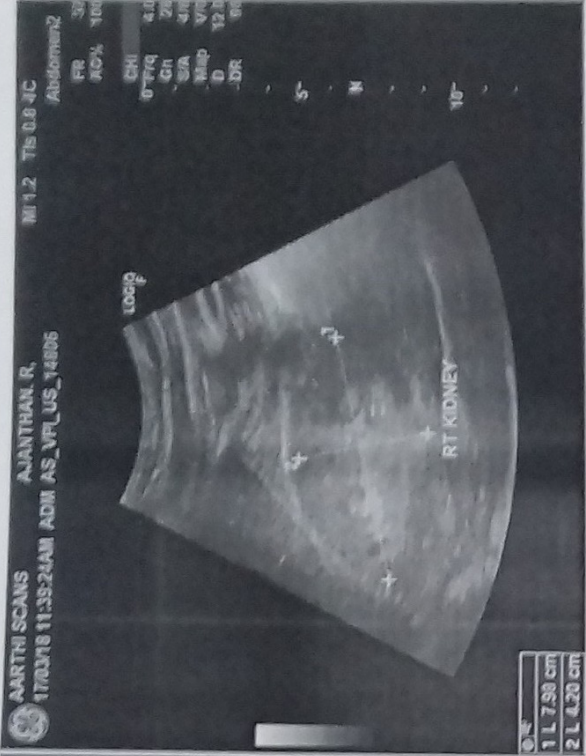
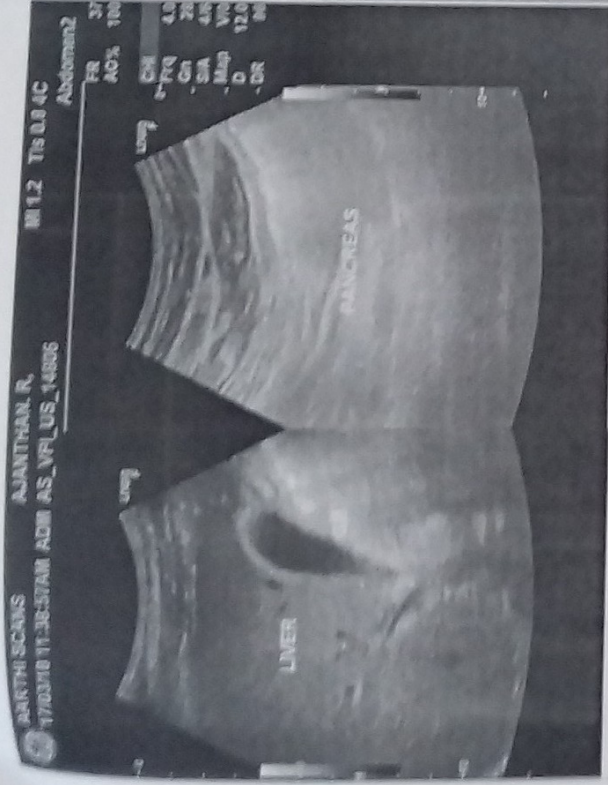
IMPRESSION:

- ❖ Normal sonographic study of Liver, GB, Spleen, Pancreas, Both Kidneys, Bladder and Prostate.

DR. K.MANOCHARAN, MD, DMRD.,
CONSULTANT RADIOLOGIST.

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• **PALAYAMKOTTAI**: Lakshmi Complex, North High Ground Road, Ph: 0462-258 1353 • **TENKASI** : 242, Sumba Street, Ph: 04633-223211, Mobile: 99401 60511
• **TUTICORIN** : 40, Palai Road, Ph: 0461-232 7353, Mobile: 99401 10515 • **KOVILPATTI** : 14-D, Santhai Pettai Road, Ph: 04632-228626, Mobile: 99400 22444
• **MADURAI** : 4, Dr. Thangaraj Salai, Madurai Ph: 0452-2521353, Mobile: 99400 80507 • **RAJAPALAYAM**: 64, Kamaraj Nagar, 2nd Street, Ph: 04563-225101, Mobile: 99401 10504

Note : This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters



NAME :	MR. E. MUTHU KUMAR	AGE/SEX	29Y/M
BRANCH :	TIRUNELVELI-PLYM	SID NO :	17009973
REF. BY :	GOVT.SIDDHA MEDICAL COLLEGE	SID DATE	17/07/2017

USG ABDOMEN & PELVIS

LIVER:

Is normal in size and uniform in echo texture.
Intrahepatic biliary radicles and CBD appear normal.
Portal and hepatic veins appear normal.

GALL BLADDER:

Is adequately distended. No internal echoes are seen.
Wall thickness is normal.

PANCREAS:

Appears normal in size and it shows uniform echo texture.

SPLEEN:

Is normal in size and uniform in echogenicity.

KIDNEYS:

RT. Kidney measures 9.6 x 4.5cms.

A calculus of size 5.4mm is visualized in the mid pole of the right kidney.

LT.Kidney measures 10.0 x 4.2cms.

Cortico medullary differentiation is maintained on both sides.
Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal in contour. No intra luminal echoes are seen.
Urinary bladder wall thickness is normal.

PROSTATE:

Measures 3.4 x 4.2 x 3.0cms. Vol: 22.3cc.

RIF:

Appears normal. No free fluid.

IMPRESSION:

- ❖ **Right renal calculus.**
- ❖ Normal sonographic study of Liver, GB, Spleen, Pancreas, Left kidney, Bladder and Prostate.



DR.SHANTH VICTOR, MBBS, RDMS (USA).

•TIRUNELVELI: 0462-2501353, Mobile: 98430 40346
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•MADURAI : 4, Dr. Thangaraj Salai, Madurai. Ph:0452-2521353, Mobile:99400780507

•THANJAVUR : 22/1, Pudukoottai Rd, Ph:279914, 279917, Mobile:87544 38504, 99529 69814
•TENKASI : 242, Samba Street, Ph:04633-223211, Mobile:99401 60517
•KOVILPATTI : 14-D, Santhai Pettai Road, Ph:04632-228636, Mobile:99400 22448
•RAJAPALAYAM: 64, Kamaraj Nagar, 2nd Street, Ph:04563-225107, Mobile:99401 10504

Note : This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters



NAME	MR.E. MUTHUKUMAR	PATIENT ID	AS_PLM_US_011709
ACCESSION NO	17_011709_172267	AGE/GENDER	28Y / MALE
REFERRED BY	DR.GOV.T.SIDDHA MEDICAL COLLEGE	DATE	04-SEP-2017

USG ABDOMEN & PELVIS

LIVER:

Is normal in size and uniform in echo texture.

Intrahepatic biliary radicles and CBD appear normal.

Portal and hepatic veins appear normal.

GALL BLADDER:

Is adequately distended. No internal echoes are seen. Wall thickness is normal.

PANCREAS:

Appears normal in size and it shows uniform echo texture.

SPLEEN:

Is normal in size and uniform in echogenicity. •

KIDNEYS:

RT. Kidney measures 9.4 x 3.4cms.

A calculus of size 4.6mm is visualized in the mid pole of the right kidney.

LT.Kidney measures 11.3 x 4.2cms.

Cortico medullary differentiation is maintained on both sides.

Pelvicalyceal system on both sides appears normal.

BLADDER:

Is normal in contour. No intra luminal echoes are seen. Urinary bladder wall thickness is normal.

PROSTATE:

Measures 3.1 x 3.4 x 3.0cms. Vol: 16.1cc.

RIF:

Appears normal. No free fluid.

IMPRESSION:

- ❖ **Right renal calculus.**
- ❖ Normal sonographic study of Liver, GB, Spleen, Pancreas, Left kidney, Bladder and Prostate.

DR.SHANTH VICTOR, MBBS, RDMS (USA).
CONSULTANT SONOLOGIST.

• TIRUNELVELI : 177, TVM Road, Vamarapettai, Ph:0462-2501353, Mobile : 98430 40346 • THANJAVUR : 22/1, Pudukottai Rd, Ph:279914,279917, Mobile:87544 38504, 99529 69814
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• TUTTICORIN :40, Palai Road, Ph : 0461 - 232 7353, Mobile : 99401 10515 • KOVILPATTI : 14-D, Santhai Pettai Road, Ph:04632-228626, Mobile:99400 22448
• MADURAI : 4, Dr. Thangaraj Salai, Madurai. Ph:0452-2521353, Mobile:99400 80507 • RAJAPALAYAM: 64, Kamaraj Nagar, 2nd Street, Ph:04563-225101, Mobile:99401 10504

Note : This imaging modality is having its own limitations, Hence this report should be correlated with clinical features and other parameters



SUBHAM NURSING HOME

1, AMMAIAPPAR SANNATHI STREET, AMBASAMUDRAM - 627401.

© 252905-250058

ABDOMINAL SCAN REPORT

NAME : Mr. Annamalai AGE : 33 SEX : M
 REF. BY. : Dr. DATE : 30.4.18

Dear Doctor,

Thank you for your Referral,

LIVER

SIZE : Normal
 ECHOGENICITY : uniform
 REMARKS :

GB

SIZE : Normal
 WALL : No calculi.

CALCULUS

SPLEEN :

SIZE : Normal
 ECHOGENICITY :

PANCREAS

SIZE : Normal
 ECHOGENICITY :

RIGHT KIDNEY

SIZE
ECHOGENICITY
COLLECTING SYSTEM

: 10.0 x 4.2 cm
: Peliculyceal
: Pattern is normal
: There are two
: calculi seen in
: lower calyx.
REMARKS
(the 4mm, 5mm)

10.2 x 5.4 cm
Normal
sinus region is
echogenic
No calculus is
seen.

BLADDER

WALL
CALCULUS
RETROPERITONIUM

: Normal
: No calculus.
:

UTERUS

: Endometrium
: Myometrium

Pr — is normal

Rt Ovary

Lt Ovary

POD

IMPRESSION

: Right renal calculus is



BARANI SCANS

Serving with Humanity

Registered with AERB, Lab Accredited by CMC Vellore

Name	Mr. ANNA MALAI	24.05.2018
Age/ Sex	23 Y/M	5890 /USG

USG ABDOMEN

Thanks for reference

Liver

Liver parenchyma shows normal size (about 12.5cms) echogenecity and morphology. No evidence of focal lesion is seen. IHBR are not dilated. Portal vein and its major branches appear normal.

GB:

Gall bladder appears normal. No abnormal echogenecity or evidence of calculus seen. CBD is not dilated.

Pancreas

Pancreatic parenchyma appears normal. Pancreatic duct is not dilated. No evidence of calcification or abnormal echogenecity is seen.

Spleen:

Parenchyma appears normal in size (about 9.8cms) and echogenecity. No evidence of focal lesion is seen.

Kidneys:

Right kidney measures 10.3x5.5cms. Left kidney measures 11.2x5.8cms.

Parenchymal echoes are normal. CMD is preserved. Pelviccalyceal system is normal.

Ureters are not dilated. **There is a calculus measuring about 5mms present in middle calyx of right kidney.**

Urinary Bladder:

Bladder appears normal. No evidence of calculus is seen. No significant wall thickening is seen.

Prostate:

Prostate is normal in size and echogenecity.

Retroperitoneal structures appear normal.

No significant inflammatory changes or mass in RIF.

No significant free fluid in abdomen and pelvis.

IMPRESSION:

- **Right renal calculus.**
- **Normal sonographic study of liver, GB, pancreas, spleen, left kidney, bladder and prostate.**

te: This imaging modality has its own limitations. Hence it should be **Dr. S. M. MOHIDEEN FATHIMA MD. (RD)**
Patient's identity is not verified.

Dr. S. M. MOHIDEEN FATHIMA MD. (RD)
CONSULTANT RADIOLOGIST
Ph. No: 8220714812



3, Thiruchendur Road, (Near Murugankuruchi Signal)
Iyambakkottai, TIRUNELVELI - 627 002.

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HITECH DIAGNOSTIC CENTRE

The Extra Care Lab
No.935, GKS Tower, Poonamallee High Road, Purasawalkam, Chennai - 600 084



An ISO 9001 : 2015
Certified Organisation

Patient : P0114073 **Mr. MURUGAN (40/M)**

SID.No. : **000132**

Branch : **PALAYAMKOTTAI**

Referrer : **GOVERNMENT SIDDHA HOSPITAL.**

Address : **PALAYAMKOTTAI
TIRUNELVELLI**

Date : 04/01/2018

Rec Time : 11:40:41

Rpt Date : 12/01/2018

Rpt Time : 09:45:58

Page # : 1

Copy of the report

Source : **DR.T.SEETHA LAKSHMI,M.D., (S)**

Test	Result	Biological Reference Interval
------	--------	-------------------------------

Sample collected and sent

TEST REPORT

URINE - BIOCHEMISTRY

RENAL STONE ANALYSIS

Method : Fourier Transform Infrared Spectroscopy

The calculi consist of Whewellite and Weddellite.

*** NOTE *** : REPORT ENCLOSED.

Ganesan

DR.SP.GANESAN. MBBS., DCP.,

* End Of Report *

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Dr. SP. Ganesan, MBBS, DCP, eMBA
Medical Director

Dr. Radhi Lawrence, AB (path)
Chief Pathologist

Dr. Priya, MD
Consultant Microbiologist

Mrs. Malini Parasuraman, M.Sc, M.phil
Chief of Lab Services

a Unit of Dr. Ganesan's Hitech Diagnostic Centre Pvt. Ltd.

P.T.O

ANNEXURE VII

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL, PALAYAMKOTTAI – 2

Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjil Kudineer”**

Form I

Screening and Selection proforma

1. OP No. : _____ Date : _____
2. Name : _____
3. Age : _____ ☐ 1.Vatha Kaalam (0-33 years)
2.Pitha Kaalam (34 - 66 years)
4. Gender : ☐ 1.Male 2.Female
5. Blood group: _____
6. Address :

7. Contact No. : _____

Criteria for Selection:

Yes ☐ 1 No ☐ 2

1. Age 20-60 years ☐
2. Both Sex : Male ☐ Female ☐
3. Patient with appropriate symptoms of

Renal Colicky Pain (நாபிக்கு கீழே சுருக்கென்று வலி உண்டாகும்)	
Nausea (or) Vomitting (குமட்டல் அல்லது வாந்தி)	

Haematuria (சிறுநீருடன் ரத்தம் கலந்து வெளியாதல்)	
Oliguria (சிறுநீர் குறைந்து இறங்குதல்)	
Dysuria (நீர் எரிச்சலுடன் கடுத்து இறங்குதல்)	
Sweating (வியர்வை தோன்றுதல்)	

4. Patient who are willing to sign informed consent and undergo laboratory investigations ☐

Criteria for Exclusion :

Yes ☐ 1 No ☐ 2

- | | |
|-----------------------------------------|--------------------------|
| 5. H/o. Pregnant & lactating women | <input type="checkbox"/> |
| 6. H/o. Diabetes mellitus | <input type="checkbox"/> |
| 7. H/o. Chronic appendicitis | <input type="checkbox"/> |
| 8. H/o. Pyelonephritis | <input type="checkbox"/> |
| 9. H/o. Cholecystitis | <input type="checkbox"/> |
| 10. H/o. Recurrent UTI | <input type="checkbox"/> |
| 11. H/o. Systemic Hypertension | <input type="checkbox"/> |
| 12. H/o. Chronic Kidney Disease | <input type="checkbox"/> |
| 13. H/o. Bilateral Obstructive uropathy | <input type="checkbox"/> |

A patient is eligible for admission

If “Yes” to SI. No. 1-4 ☐ & “No” to 5-13 ☐

If admitted : OPD ☐ IPD ☐

Enrolment No : _____

Date : _____

Signature of the Guide

Signature of the Investigator

Signature of the HOD

GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,

PALAYAMKOTTAI – 2

Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjil Kudineer”**

Form IA

History Taking Proforma

1. Enrollment Number : _____ **OP / IP: No.** _____

2. Chief Complaints

Chief Complaints	Present	Absent	Duration
Renal Colicky Pain (நாபிக்கு கீழே சுருக்கென்று வலி உண்டாகும்)	<input type="checkbox"/>	<input type="checkbox"/>	
Nausea (or) Vomitting (குமட்டல் அல்லது வாந்தி)	<input type="checkbox"/>	<input type="checkbox"/>	
Haematuria (சிறுநீருடன் ரத்தம் கலந்து வெளியாதல்)	<input type="checkbox"/>	<input type="checkbox"/>	
Oliguria (சிறுநீர் குறைந்து இறங்குதல்)	<input type="checkbox"/>	<input type="checkbox"/>	
Dysuria (நீர் எரிச்சலுடன் கடுத்து இறங்குதல்)	<input type="checkbox"/>	<input type="checkbox"/>	
Sweating (வியர்வை தோன்றுதல்)	<input type="checkbox"/>	<input type="checkbox"/>	

Other Presenting Complaints

☐ Present

☐ Absent

If Present Specify : _____

3. History of present illness

a. Onset of disease

☐ 1.Acute

☐ 2.Insidious

b. Duration of disease _____

4. History of previous illness:

Yes ☐ 1

No ☐ 2

a. Past illness of Urolithiasis ☐

i. If Yes details _____

b. Others ☐

i. If Yes details _____

5. Family History

Yes ☐ 1

No ☐ 2

a. Whether this problem runs in family ☐

i. If yes mention the relationship of the affected persons _____

b. History of previous investigation if any _____

6. Personal History

a. **Marital Status** ☐

1.Married

2.Unmarried

b. **Having Children** ☐

1.Yes

2.No

i. If Yes Number of Children : _____

c. **Educational Status** ☐

1.Illiterate

2.Semiliterate

3.Middle School

4.Highschool

5.Higher technical education

Others specify _____

d. **Occupational history** ☐

1.Desk work

2.Field work

3.Field work with intellectuals

4.Field work with physical labours

Indicate nature of work _____

e. **Dietary Habit** ☐

- 1.Vegetarian 2.Non Vegetarian

f. **Fluid intake** ☐

1. Less than 1 Litre 2. 1 – 2 Litres
3. 2 – 3 Litres 4. More than 3 Litres

g. **Sleep** ☐

1. Good 2.Disturbed 3.Insomnia

h. **Addiction** Yes ☐ 1 No ☐ 2

1.Smoking: ☐

If Yes, total duration in year's _____

2.Alcohol: ☐

If Yes, total duration in year's _____

3.Tobaco chewing: ☐

If Yes, total duration in year's _____

4.Coffee / Tea / Aerated Chilled drinks : ☐

If Yes, total duration in year's _____

Any other (specify): _____

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI - 2.**

Department of Pothu maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjal Kudineer”**

Form II- Clinical Assessment Proforma

Enrollment No : _____ OP / IP. No. _____

Date : BFT _____

AFT _____

I. GENERAL EXAMINATION

		Before Treatment	After Treatment
1.	Height (cm)		
2.	Weight (kg)		
3.	Temperature (F°)		
4.	Pulse rate (min)		
5.	Heart rate (min)		
6.	Respiratory rate (min)		
7.	Blood Pressure (mm/Hg)		
8.	BMI		
9.	Anaemia		
10.	Jaundice		
11.	Cyanosis		
12.	Lymphadenopathy		
13.	Pedal edema		
14.	Clubbing		
15.	Jugular venous pulsation		

Deformities Yes ☐ No ☐

If yes specify : _____

II. SYSTEMIC EXAMINATION:

1. Urogenital system:

- a. Inspection :
- b. Palpation :
- c. Percussion :

2. Other Systems:

- a. Cardiovascular system :
- b. Respiratory system :
- c. Central Nervous system :
- d. Gastro – intestinal system:
- e. Endocrine system :

III. SIDDHA SYSTEM OF EXAMINATIONS:

i. Kaalam:

☐

- 1.Kar kaalam - Aavani, Purattasi (Aug 15- Oct 14) ☐
- 2.Koothir kaalam - Iyppasi, Karthigai (Oct 15- Dec 14) ☐
- 3.Munpani kaalam - Markazhi, thai (Dec 15- Feb 14) ☐
- 4.Pinpani kaalam - Masi, Panguni (Feb 15 – Apr 14) ☐
- 5.Elavenil kaalam - Chithirai, vaikasi (Apr 15-Jun 14) ☐
- 6.Muthuvenil kaalam - Aani, Aadi (June 15 – Aug 14) ☐

ii. Nilam:

S.No	Land where patient lived most	Place of birth
1.	Kurinji <input type="checkbox"/>	Kurinji <input type="checkbox"/>
2.	Mullai <input type="checkbox"/>	Mullai <input type="checkbox"/>
3.	Marutham <input type="checkbox"/>	Marutham <input type="checkbox"/>
4.	Neithal <input type="checkbox"/>	Neithal <input type="checkbox"/>
5.	Paalai <input type="checkbox"/>	Paalai <input type="checkbox"/>

iii. Imporigal (Sensory Organs)

			Before Treatment		After Treatment	
			N	A	N	A
1.	Mei (Visumbu)	1. Temperature Increased <input type="checkbox"/> Decrease <input type="checkbox"/> Normal <input type="checkbox"/>				
		2. Oedema in any parts of the body Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Sevi (Vali)	Aid of Hearing Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
3.	Kan (Thee)	Visual disturbances Yes <input type="checkbox"/> No <input type="checkbox"/>				
4.	Naaku (Appu)	Perception of taste Sweet <input type="checkbox"/> Sour <input type="checkbox"/> bitter <input type="checkbox"/> Salt <input type="checkbox"/> Astringent <input type="checkbox"/> Pungent <input type="checkbox"/>				
5.	Mookku (Prithivi)	Perception of smell N <input type="checkbox"/> A <input type="checkbox"/> Mucous Secretion N <input type="checkbox"/> A <input type="checkbox"/>				

iv. Kanmendheriyam (Motor Organs)

			Before Treatment		After Treatment	
			N	A	N	A
1.	Vai (Visumbu)	Any Speech disturbance Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Kal (Vaayu)	Any disturbance in Walking Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Kai (Thee)	Any disturbances in Iduthal Present <input type="checkbox"/> Absent <input type="checkbox"/> Any disturbances in Ettral Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Eruvai (Appu)	Disturbances associated with defecation Present <input type="checkbox"/> Absent <input type="checkbox"/>				
5.	Karuvai (Prithivi)	Having disorders of Ejaculation Present <input type="checkbox"/> Absent <input type="checkbox"/> Menustration Present <input type="checkbox"/> Absent <input type="checkbox"/>				

v. Uyirthathukkal

a) Vatham:

			Before Treatment		After Treatment	
			N	A	N	A
1.	Pranan (Vali)	Difficulty in Inspiration P A <input type="checkbox"/> <input type="checkbox"/> Expiration Sneezing Coughing Swallowing Spit out Belching				
2.	Abanan (Theyu)	Difficulty in Ejaculation P A <input type="checkbox"/> <input type="checkbox"/> Menstruation Urination Defecation				
3.	Vyanan (Veli)	1. Difficulty in Walking Blinking of eyes Awakening Movements of Internal & External organs 2. Differentiating the touch, Pain, Temperature, Pressure P A <input type="checkbox"/> <input type="checkbox"/>				
4.	Uthanen (Prithivi)	Any changes in Udalan vanmai Natural immunity Colour of the body Perversion in thinking P <input type="checkbox"/> A <input type="checkbox"/>				

5.	Samanan (Appu)	Disturbances in Other Vayus Present <input type="checkbox"/> Absent <input type="checkbox"/> Appetite Increased <input type="checkbox"/> Normal <input type="checkbox"/> Decreased <input type="checkbox"/>				
6.	Nagan	Interested in Learning Present <input type="checkbox"/> Absent <input type="checkbox"/> Difficulty in Eyelid movement Present <input type="checkbox"/> Absent <input type="checkbox"/>				
7.	Koorman	Difficulty in vision Present <input type="checkbox"/> Absent <input type="checkbox"/> Difficulty in Closure mouth Present <input type="checkbox"/> Absent <input type="checkbox"/> Yawning Increased Present <input type="checkbox"/> Absent <input type="checkbox"/> Yawning Decreased Present <input type="checkbox"/> Absent <input type="checkbox"/> Lacrimation Increased Present <input type="checkbox"/> Absent <input type="checkbox"/> Lacrimation Decreased Present <input type="checkbox"/> Absent <input type="checkbox"/>				
8.	Kirukaran	Disturbances in Nasal Secretion Present <input type="checkbox"/> Absent <input type="checkbox"/> Disturbances in Salivation Present <input type="checkbox"/> Absent <input type="checkbox"/> Difficulty in Sneezing Present <input type="checkbox"/> Absent <input type="checkbox"/> Difficulty in Coughing Present <input type="checkbox"/> Absent <input type="checkbox"/>				

9.	Devathathan	Lack of Concentration Present <input type="checkbox"/> Absent <input type="checkbox"/> Fatigue Present <input type="checkbox"/> Absent <input type="checkbox"/> Anger Present <input type="checkbox"/> Absent <input type="checkbox"/>				
10.	Thanajeyan	Dropsy Present <input type="checkbox"/> Absent <input type="checkbox"/>				

b) Pitham

			Before Treatment		After Treatment	
			N	A	N	A
1.	Prasagam	Disturbances in Digestion Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Ranjakam	Changes in Colour of blood Pallor <input type="checkbox"/> Red <input type="checkbox"/> Blue <input type="checkbox"/>				
3.	Sathagam	Have will power to complete the given task Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Alosagam	Have the ability to identify the familiar Subjects Present <input type="checkbox"/> Absent <input type="checkbox"/>				
5.	Prasagam	Skin texture Glowing <input type="checkbox"/> Non Glowing <input type="checkbox"/>				

c) Iyam

			Before Treatment		After Treatment	
			N	A	N	A
1.	Avalambagam	Imbalance in Other Iyam Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Kilethagam	Dryness in Mouth Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Bothagam	Perversion in taste perception Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Tharpagam	Burning Sensation felt in eyes Present <input type="checkbox"/> Absent <input type="checkbox"/>				
5.	Santhigam	Restriction in movement of any joints Present <input type="checkbox"/> Absent <input type="checkbox"/>				

vi) Seven Udal Thathukkal

	Saaram		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Indigestion	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Ex. Salivation	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Heaviness felt all over the body	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Wheezing	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
5.	Flatulence	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
6.	Cough	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
7.	Increased Sleep	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

	Decreased				
1.	Roughness in skin	Present <input type="checkbox"/>	Absent <input type="checkbox"/>		
2.	Fatigue	Present <input type="checkbox"/>	Absent <input type="checkbox"/>		
3.	Sound intolerance	Present <input type="checkbox"/>	Absent <input type="checkbox"/>		
4.	Body pain	Present <input type="checkbox"/>	Absent <input type="checkbox"/>		
5.	Dyspnoea	Present <input type="checkbox"/>	Absent <input type="checkbox"/>		

	Seneer:		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Blisters	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
2.	Neuritis	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
3.	Loss of appetite	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
4.	Reddish eye	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
5.	Jaundice	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
6.	Psychic disturbance	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
7.	Confusion	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
	Decreased					
1.	Wish to take sour and chill foods	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
2.	Dryness	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			
3.	Pallour	Present <input type="checkbox"/>	Absent <input type="checkbox"/>			

	Oon:		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Increased muscular build around neck etc.,	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Cervical adenitis	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Abscess	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
	Decreased					
1.	Fatigueness felt over Eyes, Nose, Tongue and Body	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Disease in joints	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Shrinkage of jaw, buttocks, thigh etc.,	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

	Kozhuppu:		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Dyspnoea on light work	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Flaccidity of muscle around thigh, chest, abdomen	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
	Decreased					
1.	Low back ache	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Splenomegaly	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Loss of body weight	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

	Enbu:		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Increase in number or growth of bones and teeth	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
	Decreased					
1.	Hairfall	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Brokened hair	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Joint pain	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Loosening of teeth	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

	Moolai:		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Dropsy	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Heaviness around eyes	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Smaller joint swelling esp in fingers and toes	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
4.	Oliguria	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
5.	Chronic ulcer	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
	Decreased					
1.	Osteoporosis	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Anxiety	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
3.	Darkening in visual field	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

	Sukkilam / Suronitham		Before Treatment		After Treatment	
			N	A	N	A
	Increased					
1.	Attractive to opposite sex	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Renal calculus	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
	Decreased					
1.	Painful coitus	Present <input type="checkbox"/> Absent <input type="checkbox"/>				
2.	Blackish discolouration around genital region	Present <input type="checkbox"/> Absent <input type="checkbox"/>				

VII. KOSANGAL

	i) Annamayakosam		Before Treatment		After Treatment	
			N	A	N	A
1.	Saaram	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
2.	Seneer	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
3.	Oon	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
4.	Kozhuppu	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
5.	Enbu	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
6.	Moolai	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
7.	Sukkilam / Suronitham	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				

	ii) Pranamayakosam		Before Treatment		After Treatment	
			N	A	N	A
1.	Pranan	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
2.	Kai	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
3.	Kaal	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
4.	Vai	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
5.	Eruvai	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
6.	Karuvai	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				

	iii) Manomayakosam		Before Treatment		After Treatment	
			N	A	N	A
1.	Manam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
2.	Sabtham	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
3.	Sparisam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
4.	Rasam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
5.	Roobam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
6.	Kantham	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				

	iv) Vignanamaya kosam		Before Treatment		After Treatment	
			N	A	N	A
1.	Buthi	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
2.	Sabtham	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
3.	Sparisam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
4.	Rasam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
5.	Roobam	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
6.	Kantham	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				

	v) Anandamaya kosam:		Before Treatment		After Treatment	
			N	A	N	A
1.	Piranan	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				
2.	Suluthi	Normal <input type="checkbox"/> Affected <input type="checkbox"/>				

8. ENVAGAI THERVUGAL

1. Naadi: BFT _____ AFT _____
V ☐ P ☐ K ☐ VP ☐ VK ☐ PV ☐
PK ☐ KV ☐ KP ☐ MUKKUTRAM ☐

2. Sparisam: BFT _____ AFT _____
Warmth ☐ Chillness ☐ Roughness ☐
Ex. Heat ☐ Greasy ☐ Excessive sweat ☐ Rashes ☐

3. Na: BFT _____ AFT _____
Coating ☐ Increased Salivation ☐ Dryness ☐
Pallour ☐ Redness ☐ Taste perception ☐

4. Niram: BFT _____ AFT _____
Black ☐ Yellow ☐ Reddish ☐

5. Mozhi: BFT _____ AFT _____
Hoarse voice ☐ histery voice ☐ Stammering ☐

6. Vizhi: BFT _____ AFT _____
Palour ☐ Reddish ☐ Oedema ☐ lacrimation ☐
Visual disturbances Present ☐ Absent ☐

7. Malam: BFT _____ AFT _____

Colour of the stools _____

Loose stools Present ☐ Absent ☐

Hard stools Present ☐ Absent ☐

Pain during defecation Present ☐ Absent ☐

Bleeding per rectum Present ☐ Absent ☐

8. Neer

i) Niram: BFT _____ AFT _____

Yellow ☐ Green ☐ Black ☐ White ☐

Red ☐

ii). Manam: BFT _____ AFT _____

Ketotic odour ☐ Fleshy odour ☐ Charred odour ☐

iii). Edai: BFT _____ AFT _____

Haematuria ☐ Dysuria ☐ Resembles limestone water ☐

Mixed with calculi / fleshparts ☐

iv). Nurai: BFT _____ AFT _____

Increased ☐ Decreased ☐

v) Enjal : BFT _____ AFT _____

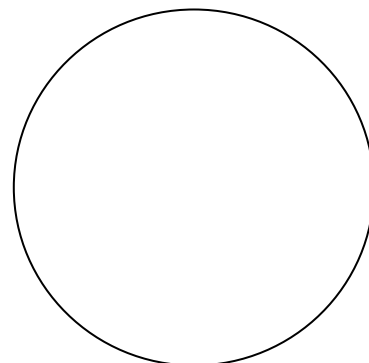
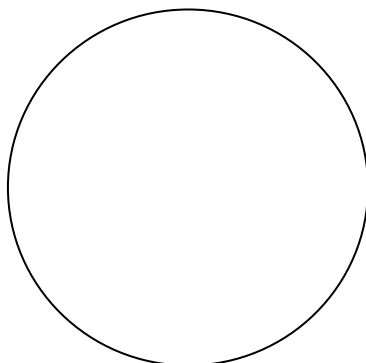
Oliguria ☐ Dripping ☐

Polyuria ☐ Anuria ☐

9. Neikuri

Sathiyakuri

Asathiyakuri



9. 14 VegangalPresent ☐Absent ☐**1. Habits of controlling**a. Thummal ☐b. Siruneer ☐**11. Thega thathuvam**

S.No		Vatham		Pitham		Kapham	
1.	Physique	Lean built		Medium build		Well built	
2.	Strength	Low strength		Medium strength		Good strength	
3.	Complexion	Glowing dark or white		pinkish or yellowish		Fair, Soft Smooth skin	
4.	Hair	Black & Brokened hair		Early graying yellow shades in hair		Blackish hair	
5.	Eyes	Rounded white conjuctiva		Yellowish or reddish conjuctiva		Broad and wide redness in corners	
6.	Eyelids	Thickened		Thinned		With denser shining eyedashes	
7.	Speech	Clear-cur or obscure speed		Excessive speech		Sound speech	
8.	Sleep	Less		Moderate		Sound	
9.	Dream	Activity, running, flying, frightening		Violence, Fire, Anger, Passian, the sun		Romance, Sentiment, Water and Snow	
10.	Food intake	Excessive food		Less food		Less food	
11.	Likes	Sweet, sour salt		Sweet, Astringent, Bitter		Bitter Astringent, pungent,	
12.	Wish to take	Hot foods		Cold foods		Warm foods	
13.	Thresh holding level to appetite	Less		Nil		Well	

V ☐P ☐K ☐VP ☐VK ☐PV ☐PK ☐KV ☐KP ☐MUKKUTRAM ☐

THEGI_____

12. MANOTHATHUVAM

S.No	Satvam		Rasatham		Thamarasm	
1.	Condescension		Confidence (Ookam)		Promiscuity (Ozhukkanminmai)	
2.	Controlling the Imporigal		Wisdom (Gnanam)		Lust / Fetishism (Kaamam)	
3.	Wisdom (Gnanam)		Valiant (Veeram)		Anger (Sinam)	
4.	Penance (Thavam)		Moralist (Aram)		Bloodshed (kolai)	
5.	Ascendant (Menmai)		Penance (Thavam)		Laziness (Sombal)	
6.	Reticence (Mounam)		Charity (Egai)		Excessive Sleep	
7.	Rightness (Vaimai)		Query (Kelvi)		Gluttony (Perundi)	

GUNAM_____

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI - 2.**

Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjal Kudineer”**

Form II A

CLINICAL ASSESSMENT BEFORE AND AFTER TREATMENT

Enrollment No : _____ OP / IP. No. _____

Date : BFT _____

AFT _____

CLINICAL SYMPTOMS

Urolithiasis Symptom Score (USS)

(Circle relevant number on each line)

Symptoms	Before Treatment	Duration	After Treatment days				
			7 th	14 th	21 st	28 th	35 th
1. Pain / Colic 0 - No Pain 1 – Mild Pain 2 – Moderate Pain 3 – Severe Pain							
2. Haematuria 0 - No Haematuria 1 – Microscopic 2 – Persistent 3 – Gross							
3. Dysuria 0 - No Dysuria 1 – Mild Dysuria 2 – Moderate Dysuria 3 – Severe Dysuria							
4. Stone 1 – Single Stone 2 – Multiple Stone							
5. Size of Stones 0 - Nil 1 – 1 – 3 mm 2 – 4 – 5 mm 3 – above 5mm							

6. Position of stone in kidney 0 - No stone in kidney 1 – Pelvic ureteric junction 2 – Pelvis of kidney 3 – Calyces of Kidney							
7. Position of stone in ureter 0 - No stone in ureter 1 – lower part in ureter 2 – middle part in ureter 3 – upper part in ureter							
8. Position of stone in bladder 0 - No stone in bladder 1 – Base of bladder 2 – Intramural ureter							

Total scoring - 22

1 – 7 : Mild, 8 – 14 : Moderate, 15 – 22: Severe

Symptoms scores

Before Treatment :

After Treatment :

Signature of the Guide

Signature of the Investigator

Signature of the HOD

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Form III

LABORATORY INVESTIGATION PROFORMA

Enrollment No : _____ OP / IP. No. _____

Date : BFT _____

AFT _____

LAB INVESTIGATION

BLOOD INVESTIGATION		BT	AT
TC (Cells / cu.mm)			
DC (%):	P:		
	L:		
	E:		
ESR (mm/hr)	½ hr		
	1hr		
Hb (gms %):			
Blood Sugar (mg/dl):	Fasting (F)		
	Post Prandial (PP)		
	Random (R)		
Blood Urea:			
Blood Creatinine:			
Serum Cholesterol:			
Bilirubin:			
URINE INVESTIGATIONS			
Specific gravity			

pH			
Albumin			
Sugar			
Deposits	Pus cells		
	Epithelial cells		
	RBC's		
	Casts / Crystals		
Bile Salts :			
Bile Pigments:			

USG ABDOMEN AND PELVIS

		Size of the Kidney	Site of the Calculus	Number of Calculus	Size of the Calculus	Hydronephrosis
Right Kidney	BFT					
	AFT					
Left Kidney	BFT					
	AFT					

Specific Investigation:

Stone Analysis:

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI - 2.**

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(Urolithiasis) with evaluation of the trial drug “Siru Nerunjil Kudineer”**

Form IV (A)

PATIENT CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms easily understood by the patient.

Name of the Investigator : Dr. T. SEETHALAKSHMI

Date :

Signature of the Investigator:.....

CONSENT BY PATIENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my body functions.

I am also aware of my right to opt out of the trial at any time during the course of the trial without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to be included

As a subject in An open labelled randomized clinical trial of polyherbal formulation of **Siru Nerunjil Kudineer** for **Kalladaippu** (Urolithiasis)

.....
Signature / thumb impression
of the subject

.....
Signature/thumb impression
of the witness

Name :

Name :

அரசினர் சித்த மருத்துவக் கல்லூரி மற்றும் மருத்துவமனை,
பாளையங்கோட்டை,
பட்டமேற்படிப்பு பொது மருத்துவத்துறை.
கல்லடைப்பு நோய்க்கு மருந்தாக சிறுநெருஞ்சில் குடிநீர்
பரிகரிப்புத்திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஒப்புதல் படிவம்

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வு குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி :

கையொப்பம் :

இடம் :

பெயர் :

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறையைப் பற்றியும் தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனைப் பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி தீருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு **கல்லடைப்பு நோய்க்கு ” சிறுநெருஞ்சில் குடிநீர் ”** மருந்தின் பரிகரிப்புத்திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

கையொப்பம்:

பெயர் :

தேதி:

சாட்சிக்காரர் கையொப்பம் :

இடம்:

பெயர்:

உறுவுமுறை :

நெறியாளர் கையொப்பம்

ஆராய்ச்சியாளர் கையொப்பம்:

துறைத்தலைவர் கையொப்பம்

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI – 2**

Department of Pothu Maruthuvam

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(Urolithiasis) with evaluation of the trial drug “Siru Nerunji Kudineer”**

Form IV (B) – WITHDRAWAL FORM

Enrollment No: _____

OP / IP No: _____

Date: _____

Date of trial commencement : _____

Date of withdrawal from trial : _____

Reasons for withdrawal :

Yes

1

No

2

1. Long absence of reporting

☐

2. Irregular treatment

☐

3. Shift of locality

☐

4. Increase in severity of symptoms

☐

5. Development of severe adverse drug reactions

☐

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI - 2.**

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjil Kudineer”**

Form IV (C) – PATIENT INFORMATION SHEET

Name of the Investigator : T.Seethalakshmi

**Name of the College : Govt. Siddha Medical College & Hospital
Palayamkottai**

**INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN
CLINICAL TRIAL**

I, DR.T.SEETHALAKSHMI studying M.D(Siddha) at Govt. Siddha Medical College, Palayamkottai, doing a clinical trial on “KALLADAIPPU” (Urolithiasis). You are invited to participate in this clinical study. The clinical study is aimed to evaluate selected Siddha drug for its efficacy in the treatment of Urolithiasis.

In this regard, I am in need to ask you a few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. And it is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to answer any specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to develop medicine for KALLADAIPPU (UROLITHIASIS). About 40 consenting patients will be included in this study.

KALLADAIPPU (UROLITHIASIS) is being treated in GSMC&H with many Siddha formulations. As a part of M.D(S) research programme and developing new efficacious medicine, I propose to study the SIRU NERUNJIL KUDINEER formulation for treating KALLADAIPPU (UROLITHIASIS). This formulation has been mentioned in Siddha literature.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the trial drug.

DETAILS OF THE TRIAL DRUG:

Trial Medicine: Siru Nerunjil Kudineer

Dosage : 40 ml (bd)

Duration : 30 days.

You can receive medicines free of cost. You have visit GSMC&H every 2 days and collect drugs for 2 days. After completion of 30 days the effect of treatment will be assess by using clinical and laboratory parameters also.

The information I am collecting in this study will remain between you and the Co-investigator (myself). I will ask you few questions through a questionnaire. The questionnaire will take approximately 20 minutes of your time. I will not write your name on this form. I will use a code instead.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact T. SEETHALAKSHMI, PG student (Cell No : 9486134159) cum investigator of this study, attached to Govt. Siddha Medical College, Palayamkottai -2.

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI – 2**

Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
(Urolithiasis) with evaluation of the trial drug “Siru Nerunjil Kudineer”**

Form IV (D) – ADVERSE DRUG REACTION FORM

Enrollment No: _____

OP / IP No: _____

Date: _____

Date of trial commencement : _____

Date of withdrawal from trial : _____

Description of adverse reaction :

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
PALAYAMKOTTAI – 2**

Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “*KALLADAIPPU*”
(Urolithiasis) with evaluation of the trial drug “*Siru Nerunjil Kudineer*”**

Form IV (E) – DRUG COMPLIANCE FORM

Enrollment No: _____

OP / IP No: _____

Date: _____

Name of the drug : **Siru Nerunjil Kudineer**

Drug issued date : _____

Drug returned date : _____

Sl No	DATE	Drug given time (Morning Time)	Drug given time (Evening Time)
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			
Day 13			

Day 14			
Day 15			
Day 16			
Day 17			
Day 18			
Day 19			
Day 20			
Day 21			
Day 22			
Day 23			
Day 24			
Day 25			
Day 26			
Day 27			
Day 28			
Day 29			
Day 30			

Signature of the Guide

Signature of the Investigator

Signature of the HOD

**GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL,
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Department of Pothu Maruthuvam

**A prospective open labeled randomized clinical trial on “KALLADAIPPU”
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FORM IV (F) – DIETARY ADVICE FORM

உணவு பழக்கவழக்கங்கள்:

உண்ணக்கூடியவை:

- குருவை, மணக்கத்தை அரிசி யாலாக்கிய சோறு உண்ண வேண்டும்.
- பார்லி அரிசிக்கஞ்சி, இளநீர் அருந்தவும்.
- முள்ளங்கி, வாழைத்தண்டு, அவரைக்காய், பூசணிக்காய், சுரைக்காய், கேரட், வெண்டைக்காய் சேர்க்க வேண்டும்.
- தாப்பூசணி, பப்பாளி, கொய்யா, எலுமிச்சை சேர்க்கலாம்.
- பசலைக்கீரை, காளானிக்கீரை, கீரைத்தண்டு, வெள்ளரி விதை உண்ணவும்.

தவிர்க்க வேண்டியவை:

- தக்காளி, முட்டைகோஸ், காலிப்ளவர், உருளைகிழங்கு, காளான்.
- பால், காபி, டீ, மதுபானம், பதப்படுத்தப்பட்ட பானங்கள் அருந்தக்கூடாது.
- முட்டை, ஐஸ்கிரீம், சாக்லேட் தவிர்க்கவும்.

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32. Theran Karisal.



The Tamil Nadu Dr. M.G.R. Medical University
69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs. **T. SEETHA LAKSHMI**.....
For participating as ~~Resource Person~~ / Delegate in the Twentieth Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

For AYUSH Post Graduates & Researchers
Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 07th to 11th March 2016.

DR.N.KABILAN, M.D.(S)
PROF & HEAD
DEPT.OF SIDDHA

Prof.Dr.PARUMUGAM, M.D.,
REGISTRAR i/c

Prof. Dr.S.GEETHALAKSHMI, M.D., Ph.D.,
VICE CHANCELLOR

GOVERNMENT SIDDHA MEDICAL COLLEGE





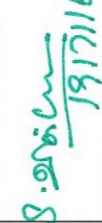

PALAYAMKOTTAI

SCREENING COMMITTEE

Candidate Reg No :

Department : Pothu Maruthuvam, Branch : I

This is to certify the dissertation topic “A Prospective open labeled randomized clinical study on “**KALLADAIPPU**” with evaluation of the trail drug “**SIRU NERUNJIL KUDINEER**” has been approved by the screening committee.

Branch	Department	Name	Signature
01	Pothu Maruthuvam	Dr.A.Manoharan MD (s) Professor	
02	Gunapadam	Dr.A.Kingsly MD (s) Associate Professor	
03	Sirappu Maruthuvam	Dr.A.S.Poongodikanthimathi MD (s) Professor	
04	Kuzhanthai Maruthuvam	Dr.D.K.Soundararajan MD (s) Professor	
05	NoiNadal	Dr.S.Victoria MD (s) Professor	
06	Nanju Nool Maruthuvam	Dr.M.Thiruthani MD (s) Professor	

Remarks :

INSTITUTIONAL ETHICAL COMMITTEE
GOVERNMENT SIDDHA MEDICAL COLLEGE, PALAYAMKOTTAI
TIRUNELVELI - 627 002
TAMIL NADU INDIA

Ph.No : 0462-2572736 / 2572737 / 2582010
Email ID : gsmc.palayamkottai@gmail.com

Fax : 0462-2582010

R.No.GSMC / 5676 / P&D / Res / IEC / 2014

Date : 20.07.2016

CERTIFICATE OF APPROVAL

Address of Ethical committee	Government Siddha Medical College Palayamkottai - 627002 Tirunelveli District
Principal investigator	Dr T.Seethalakshmi M.D (s) First Year PG Dept of Pothu Maruthuvam Reg.No :
Supervisor	Dr.A.Manoharan M.D (s) Professor & Head of the Department
Guide	Dr.G.Subash Chandran M.D (s), Ph.D Lecturer
Dissertation topic	A prospective open labeled randomized clinical trial on “ Kalladaippu ” (Urolithiasis) with evaluation of trial drug “ Siru Nerunjil Kudineer ”
Document field	1. Protocol 2. Data Collection Form 3. Patient Information Sheet 4. Consent form
Clinical / Non Clinical trial Protocol	Clinical trial protocol - Yes
Informed consent document	Yes
Any other document	Case sheet, Investigation document
Date of IEC approval & it's Number	GSMC/3-IEC/2016-I-7/20.07.2016

We approve the trial to be conducted in its presented form.

The Institutional Ethical committee expects to be informed about the process report to be submitted to the IEC at least annually of the study, any SAE occurring in the course of the study and changes in the protocol and submission of final report.

Chairman
(Signature)
(Prof.Dr.M.Logamanian PhD)

Member Secretary
(Signature)
(Prof. Dr.S.Victoria MD(s))

GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI

Certificate of Botanical Authenticity

Certified the following plant drugs used in Siddha formulation ***Siru Nerunjil Kudineer*** (Internal) for the management of ***Kalladaippu*** (*Urolithiasis*) taken up for PG Dissertation Studies by Dr.T.Seetha Lakshmi (Reg No.321511007), II year, Department of Pothu Maruthuvam are correctly identified and authenticated through Visual Inspection / Organoleptic Characters / Experience, Education and Training Morphology and Taxonomical methods.

Ingredient of Siru Nerunjil Kudineer

Sl.No	Name	Botanical Name	Family	Part used
1	Siru Nerunjil	<i>Tribulus terrestris.Linn</i>	Zygophyllaceae	Fruits
2	Koththamallii	<i>Coriandrum sativum.Linn</i>	Apiaceae	Dried Fruits

Station: Palayamkottai,

Date: 27/03/2017


Authorized Signature

Dr. S. SUTHA, M.Sc., M.Ed., Ph.D.,
Associate Professor
Dept. of Medicinal Botany
Govt. Siddha Medical College
Palayamkottai Tirunelveli - 2.

SASTRA UNIVERSITY

(A University under section 3 of the UGC Act, 1956)
THANJAVUR - 613 401, INDIA

CERTIFICATE

This is to certify that the project entitled Screening of Nerungil kudineer on ethylene glycol induced urethraliasis in rats

has been approved by the Institutional Animal Ethics Committee (IAEC), SASTRA University field on 09-09-2017.....

CPCSEA Approval Number: 483/SASTRA/IAEC/RPP

Name of Chairman / Member Secretary, IAEC :

Signature with date Dr. C. David Raj
Name of CPCSEA nominee : Dr. V. Vallaiappan

CPCSEA nominee

Chairman 09/09/2017



GOVERNMENT SIDDHA MEDICAL COLLEGE

PALAYAMKOTTAI, TIRUNELVELI - 627 002.

CONTINUING MEDICAL EDUCATION PROGRAMME

Conducted by
Post Graduate Department of Pothu Maruthuvam



This Certificate is awarded to Dr / ~~Mr~~ / ~~Mrs~~
T. SEETHA LAKSHMI
has participated in the CME Programme held on 13.06.2018 at Conference Hall Special Therapy Wing, Government Siddha Medical College, Palayamkottai, Tirunelveli. This Programme is focussed on

“NON COMMUNICABLE DISEASES”

Prof. Dr. A. MANOHARAN, M.D.(s) Ph.D.,
Head, Department of Pothu Maruthuvam (PG)

Government Siddha Medical College, Palayamkottai.

Prof. Dr. R. NEELAVATHI, M.D.(s) Ph.D.,
PRINCIPAL

Government Siddha Medical College, Palayamkottai.

Certificate

CME PROGRAMME

Conducted By

**POST GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM
GOVERNMENT SIDDHA MEDICAL COLLEGE & HOSPITAL
PALAYAMKOTTAI**

This certificate is proudly presented to Dr. T. Seeja Lakshmi P.G. Scholar
for the Participation and Implementation of "International Day of Yoga"
held on 21-06-2018 at Government Siddha Medical College & Hospital, Palayamkottai.



Yoga for Harmony & Peace

Prof. Dr. A.S. Poongodi Kanthimathi M.D (Siddha),

Head - Department of Sirappu Maruthuvam.

Prof. Dr. R. Neelavathy M.D (Siddha), Ph.D.,

Principal.



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Research Article



Anti-inflammatory activity of Akkini Chooranam – A Siddha preparation

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Abstract

Objectives: To evaluate the anti inflammatory activity of the Siddha preparation 'Akkini Chooranam ' through rat paw odema method.

Method: The paw odema volumes of the test compounds, standard and control groups were measured at 60, 240, 360 minutes after Carrageenan treatment with the help of plethysmometer. Mean increase in paw odema volume was measured and the percentage of inhibition was calculated.

Results: The results showed significant ($p < 0.01$) anti inflammatory activity when compared to control group.

Conclusion: The test drug shows potent activity at the concentration of 200mg/kg compared to standard drug, Diclofenac Sodium.

Keywords: Akkini Chooranam, Siddha, Carrageenan, Hind paw odema, Anti Inflammatory Activity

Introduction

In Siddha system, herbal products (*thavaram*) used as medicine, have studied from various Siddha literatures. The herbal plants constitute a source of raw materials ^[1]. The raw drugs are easily available much effective and safety at low cost and they can be used as home remedies too. The Siddha preparation of *Akkini Chooranam* is one among them which is effective in treating Vatha disease, Peptic ulcer, and abdominal pain ^[2]. In order to evaluate the test drug for anti inflammatory activity, experimental models using Carrageenan induced rat paw odema method was carried out.

Materials and Methods

From the Siddha text book of *Koshayi Anubaga Vaitthiya Bramma Ragasiyam*, the preparation of *Akkini Chooranam*^[3] was taken,

A) Ingredients of Akkini Chooranam^[1]:

- Chirakam (*Cuminum cyminum*. Linn)
- Thippili (*Piper longum*)
- Chukku (*Zingiberofficinale*)
- Lavangam (*Syzygiumaromaticum*.Linn)